Case: 24-1285 Document: 25-3 Page: 1 Filed: 01/10/2024 CONFIDENTIAL BUSINESS INFORMATION REDACTED ENTIRELY FROM PAGES MAS-ADD-002 - MAS-ADD-020

# **EXHIBIT 1**Confidential Business Information

# **EXHIBIT 2**Confidential Business Information

## CONTAINS CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

#### UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

#### ORDER NO. 31: DENYING RESPONDENT'S MOTION FOR SANCTIONS

(April 28, 2022)

On December 28, 2021, Respondent Apple Inc. ("Apple") filed a motion (the "Motion for Sanctions," Docket No. 1276-012) for sanctions against Complainants Masimo Corporation ("Masimo") and Cercacor Laboratories, Inc. ("Cercacor"), attaching exhibits ("Apple Exhibits") and a memorandum in support ("Apple Memo."). On January 10, 2022, Complainants filed a response in opposition to the motion ("Opposition"), attaching exhibits ("Masimo Exhibits"). On January 12, 2022, Apple filed a reply brief ("Reply").

On February 16, 2022, Apple filed a motion (the "Supp. Motion," Docket No. 1276-021) for leave to file a notice of supplemental facts regarding the Motion for Sanctions, attaching supplemental exhibits ("Supp. Exhibits"), including the deposition transcript of Joe Kiani, Masimo's Chief Executive Officer. Supp. Exhibit B. On February 28, 2022, Complainants filed an opposition to the Supplemental Motion ("Supp. Opp."), attaching supplemental exhibits ("Supp. Opp. Exhibits"). On March 3, 2022, Apple filed a reply in support of the Supplemental Motion ("Supp. Reply").

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<sup>&</sup>lt;sup>1</sup> The undersigned finds that the supplemental exhibits include information that is relevant and could not have been provided in the original Motion for Sanctions. Accordingly, the Supplemental Motion (1276-021) is hereby GRANTED.

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#### I. BACKGROUND

Complainants filed their Amended Complaint on July 7, 2021, identifying a "Masimo
Watch— as the alleged domestic industry product for four of the
five asserted patents. Amended Complaint at ¶ 86, EDIS Doc. ID 746514 (July 7, 2021).
Complainants represented that "[a] confidential sample of a Masimo Watch that embodies the
claims of the [Asserted] Patent[s] is available upon request." <i>Id.</i> at ¶¶ 47, 54, 61, 68. Attached
to the Amended Complaint is a declaration from Bilal Muhsin, the Chief Operating Officer of
Masimo, representing that "[t]he Masimo Watch Product is a watch developed by Masimo and
and that
Amended Complaint, Exhibit 27 at ¶ 4. He describes the functionality of the "Masimo
Watch Product" and represents that claim charts attached to the Amended Complaint "accurately
reflect the design of the Masimo Watch Product." <i>Id.</i> at ¶¶ 4-23. Mr. Muhsin's declaration
of the "Masimo Watch," which were attached to the Amended Complaint as
Exhibit 21. <i>Id.</i> at ¶ 8.

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Amended Complaint, Exhibit 21. Claim charts attached to the Amended Complaint rely on the

		of a "Masimo	o Watch" product	
Cas Amandad Commisint Ex	hibit 22 at 0 Evil	hihit 22 at 11	Explifit 24 at 22	

See Amended Complaint, Exhibit 22 at 9, Exhibit 23 at 11, Exhibit 24 at 22.

In discovery, Apple sought production of a sample of the "Masimo Watch." See Apple Exhibit A (Request for Production No. 124). After extensive discussions between the parties, Complainants agreed to make certain "Masimo Watch" products available for inspection. See Apple Exhibit B, Exhibit C, Exhibit D, Exhibit E, Exhibit F, Exhibit G, Exhibit H, Exhibit I. Complainants produced physical items for inspection on October 20, 2021, including a "current version of the Masimo Watch." Apple Exhibit I. Apple sought to compel the of a "Masimo Watch" and the parties participated in a teleconference with the undersigned on October 28, 2021. See Teleconference Transcript (Oct. 28, 2021), EDIS Doc. ID 755884/755885. On November 10, 2021, Complainants produced physical objects for inspection. See Apple Exhibit M (photograph

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from 11/10/21 inspection), Exhibit N (email discussion regarding inspection), Exhibit O (chart listing items for inspection).

The parties discussed the second inspection of "Masimo Watch" products during a subsequent teleconference on November 19, 2021. *See* Teleconference Transcript (Nov. 19, 2021), EDIS Doc. ID 757325. During this teleconference, Complainants were ordered to identify which of the physical objects provided for inspection they intended to rely on for the technical prong of the domestic industry requirement. *Id.* at 25-27. Complainants provided an identification on November 23, 2021. Apple Exhibit N. The parties again discussed the "Masimo Watch" physical exhibits during a teleconference on December 6, 2021. *See* Teleconference Transcript (Dec. 6, 2021), EDIS Doc. ID 758034.

On December 15, 2021, Complainants produced a physical "Masimo Watch" (labeled MASITC\_P\_127) in connection with the deposition of Bilal Muhsin. *See* Apple Exhibit S at 1 (Dec. 14 email), Exhibit T (Muhsin Dep. Tr.) at 6:2-8:1. Masimo represented that "[t]he physical Apple Exhibit S at 1 (Dec. 13 email); *see also* Exhibit T at 46:16-18 (describing the "physical Mr. Muhsin . *See* Apple Exhibit T at 35:3-36:17, 44:23-45:5. Complainants' counsel represented that the physical sample . *Id.* at 46:6-8.

In Masimo manufactured a "Masimo Watch" product and Complainants produced a sample of this product to Apple at the deposition of Masimo employee Stephen Scruggs on January 6, 2022. *See* Opposition at 19; Masimo Exhibit 59; Supp. Opp. at 2, Physical Exhibit A. Apple took the deposition of Masimo CEO Mr. Kiani on February 11, 2022,

where he discussed the development of the "Masimo Watch." Supp. Exhibit B.

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#### II. BRIEFING

Apple moves for sanctions against Complainants based on alleged misrepresentations in the Amended Complaint. Apple Memo. at 28-42. In particular, Apple identifies Complainants' representations that a physical "Masimo Watch" describing a "Masimo Watchand stating that "[a] confidential sample of a Masimo Watch . . . is available upon request." Amended Complaint at ¶¶ 47, 54, 61, 68, 86. Apple also cites the declaration of Mr. Muhsin attached to the Amended Complaint, which describes "the design of the Masimo Watch Product." Amended Complaint, Exhibit 27 at ¶¶ 4-23. Apple argues that the statements in the Amended Complaint "make crystal clear that the Complainants allege the existence of a Apple Memo. at 31. Apple contends that the representations in the Amended Complaint regarding the "Masimo Watch" were untrue based on evidence that was uncovered during discovery. Apple Memo. at 32-42. Apple submits that none of the physical items that Complainants made available for inspection *Id.* at 32-36. Apple further identifies evidence that no "Masimo Watch" *Id.* at 36. Apple argues that Complainants' inconsistent conduct during discovery is further evidence that the statements in the Amended Complaint regarding the "Masimo Watch" were false. *Id.* at 37-39. Apple submits that the appropriate sanctions in this case are termination of the investigation and the payment of Apple's attorneys' fees and costs. *Id.* at 39-42.

Complainants oppose the motion for sanctions, arguing that Apple's contentions are premised on an erroneous assumption that the domestic industry requirement requires a finished

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commercial product. Opposition at 28-32. Complainants submit that the Amended Complaint did not allege the existence of a " Id. (citing Amended Complaint at ¶ 89). Complainants submit that numerous physical "Masimo Watch" articles and were produced for inspection during discovery. *Id.* at 33. Complainants submit that a of the "Masimo Watch" , showing that the representation in the Amended Complaint regarding a was accurate. *Id.* at 34-37. Complainants argue that sanctions are not appropriate in these circumstances and the scope of Apple's requested relief is unwarranted. *Id.* at 37-39. Complainants suggest that the Administrative Law Judge should consider sanctions against Apple for its discovery conduct and allegedly false statements in the Motion for Sanctions. *Id.* at 39-42.<sup>2</sup> In reply, Apple contends that it is "clear from the Complaint itself" that "the Complaint ." Reply at 4-5. Apple submits that was intended to convey the existence of a Complainants' statements have been shown to be false, because no "Masimo Watch" that Id. at 5. Apple argues that Complainants have identified no evidence from before the filing of the Amended Complaint that shows *Id.* at 5-6. Apple submits that it clearly requested a sample of the "Masimo Watch" in discovery and that Complainants unreasonably delayed their production of physical items. *Id.* at 7-8.<sup>3</sup>

<sup>&</sup>lt;sup>2</sup> Complainants' request for *sua sponte* sanctions against Apple circumvents the notice requirements under Commission Rule 210.4(d)(1). The undersigned will not consider Complainants' request in the context of this order.

<sup>&</sup>lt;sup>3</sup> Although Apple makes numerous allegations regarding Complainants' conduct during discovery, the motion does not seek discovery-based sanctions. *See* Apple Mot. at 1-4; Memo. at 36 n.11.

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In its supplemental brief, Apple cites evidence that the "Masimo Watch"

See Supp. Exhibit B. In opposition, Complainants argue that the
Supp. Opp. at 1-2. Complainants identify the testimony of a Masimo engineer explaining
that a "Masimo Watch" device as
Supp. Opp. Exhibit 68 (Ali-Ali Dep. Tr.) at 89-90, 124-25. In reply, Apple cites testimony from
another Masimo engineer that the
See Motion Exhibit B (Scruggs Dep. Tr.) at 34-35.

#### III. LEGAL STANDARDS

Commission Rule 210.4 places an obligation on parties making representations before the Commission to certify "to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances" that:

- (1) [The submission] is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceeding;
- (2) The claims, defenses, and other legal contentions therein are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; [and]
- (3) The allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

19 C.F.R. § 210.4(c). When these obligations have been violated, the administrative law judge may "impose an appropriate sanction upon the attorneys, law firms, or parties that have violated paragraph (c) or are responsible for the violation." 19 C.F.R. § 210.4(d). "If any portion of a representation is found to be false, frivolous, misleading, or otherwise in violation of paragraph

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(c), a sanction may be imposed." *Id*. "In determining whether paragraph (c) has been violated, the administrative law judge or the Commission will consider whether the representation or disputed portion thereof was objectively reasonable under the circumstances." *Id*.

Commission Rule 210.4(d)(1)(i) provides that a party may seek sanctions by motion. 19 C.F.R. § 210.4(d)(1)(i). The burden of proving a violation of Commission Rule 210.4(c) rests with the party moving for sanctions. *See Certain Wind and Solar-Powered Light Posts*, Inv. No. 337-TA-746, Order No. 13 at 9, EDIS Doc. ID 451418 (May 11, 2011) (citing *Certain Self-Inflating Mattresses*, Inv. No. 337-TA-302, Recommended Determination at 7-8, 1990 WL 710471 (Dec. 24, 1990)).

#### IV. DISCUSSION

In consideration of the parties' arguments, the undersigned finds that sanctions are not warranted under Commission Rule 210.4(d). Although the Amended Complaint contains statements regarding the "Masimo Watch" that are susceptible to different interpretations, Apple has not shown Complainants' representations to be false, frivolous, or misleading.

Apple reads the Amended Complaint to assert the existence of a "Masimo	
Watch," but the undersigned agrees with Complainants that the Amended Complaint, when rea	d
as a whole, describes a "Masimo Watch" that	
The Amended Complaint states that "Masimo	
Amended Complaint at ¶ 86.	
Id. at ¶ 88. With respect to the patents where Complainants are relying of	)11
the "Masimo Watch" for a domestic industry, the Amended Complaint is equivocal on the issue	<u>,</u>

of whether a domestic industry exists or is in the process of being established: "To the extent it is

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determined that a domestic industry
Id.
at ¶ 86. In view of these statements, it is clear that the subsequent statement—"the Masimo
Watch is protected by one or more claims of [the asserted patents]"—refers to a product that is
. See id. The undersigned finds that it is objectively reasonable to read the
Amended Complaint to refer to a "Masimo Watch" that
Apple fails to identify any statement in the Amended Complaint explicitly representing
that the "Masimo Watch" . An Administrative Law Judge
addressed a similar situation in Certain Blu-Ray Disc Players, Components Thereof and
Products Containing Same, where a motion for sanctions was denied with respect to a
declaration regarding a complainant's domestic industry where the parties disputed certain
statements. Inv. No. 337-TA-824, Order No. 36 at 5-6, EDIS Doc. ID 499178 (Dec. 5, 2012). In
that case, the Administrative Law Judge found that "Respondents are misreading or
misinterpreting those statements to support the motion for sanctions" and "failed to show that
[the declarant] made any false, material statements in his declaration." Id. In the present motion,
Apple has misread the Amended Complaint to represent that the "Masimo Watch" was a

<sup>&</sup>lt;sup>4</sup> The Commission has recognized the possibility that a domestic industry might be shown to be in the process of being established while the development of protected articles is ongoing. *See Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing Same*, Inv. No. 337-TA-1073, Comm'n Op. at 11-13, EDIS Doc. ID 684974 (July 19, 2019) ("The development of protected articles is one aspect of the process of establishing a domestic industry relating to such articles."); *see also Certain Non-Volatile Memory Devices and Products Containing the Same*, Inv. No. 337-TA-1046, Comm'n Op. at 41-44, EDIS Doc. ID 659979 (Oct. 26, 2018) (recognizing that commercial production of domestic industry articles is not required).

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and has identified two alleg	gedly false statements in the Amended
Complaint—Complainants' representations that	t the "Masimo Watch" is
" and that a "confidential sample of a Masi	imo Watch that embodies the claims of the
[asserted patents] is available upon request." Se	ee Amended Complaint at ¶¶ 47, 54, 61, 68, 86.
As discussed below, Apple has not shown that e	either of these statements lacks evidentiary
support.	
With respect to the	, neither party has identified clear evidence
of Masimo's	. A
Masimo internal presentation submitted by App	ole identifies
Apple Exhib	oit FF at 11. <sup>5</sup>
	See Apple Memo. at 24. Mr. Muhsin testified
at his deposition that the "Masimo Watch"	
Apple Exhibit T (Muhsin Dep. Tr.) at 8:	19-22. Mr. Kiani later confirmed that
Supp. E.	xhibit B at 121-26. Apple submits that there is no
evidence that	
See Reply at 5-6. Although the evidence	does not show that
	, the
undersigned finds that the internal presentation	and the testimony of Mr. Muhsin and Mr. Kiani

<sup>&</sup>lt;sup>5</sup> A replacement for this exhibit including a confidentiality designation was separately filed on January 7, 2022.

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are sufficient evidentiary support for the allegation that the "Masimo Watch" was
In particular, the internal Masimo presentation includes
See Apple Exhibit FF at 11 (
Apple has interpreted the statement in the
Amended Complaint to refer to a
In the context of the Amended Complaint, the statement can be read to be consistent
with a, and there is sufficient evidentiary support for this allegation. <sup>7</sup>
With respect to the "Masimo Watch" samples that were referenced in the Amended
Complaint, there is no dispute that multiple "Masimo Watch" physical items
As discussed above, Apple has misinterpreted the Amended
Complaint to represent that there was a "Masimo Watch." Apple argues that in the
absence of a "Masimo Watch," however, none of Masimo's physical items embodied
the claims of the asserted patents. In response, Complainants submit that certain
See Apple Exhibit J (Response to Interrogatory No. 74) at 5 (Dec. 3, 2021
6
Masimo Exhibit 35 at 188:20-189:17.

<sup>&</sup>lt;sup>7</sup> The undersigned has made no determination as to what a preponderance of the evidence will show with respect to whether Masimo's plans for the "Masimo Watch" satisfy the requirements for establishing a domestic industry in the process of being established. The relevant issue on this motion is only whether there is sufficient evidentiary support for Masimo's allegations such that sanctions are not warranted.

#### CONFIDENTIAL INFORMATION REDACTED

## CONTAINS CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

Exhibit X (Response to Interrogatory No. 86) at 22 (Dec. 23, 2021). Mr. Muhsin testified that

Masimo Exhibit 35 (Mushin Dep. Tr.) at 26-28. Mr. Ali-Ali corroborated this
testimony. See Supp. Opp. Exhibit 68 (Ali-Ali Dep. Tr.) at 89-90, 124-25. Apple has identified
several reasons to question Complainants' contentions regarding the
"Masimo Watch" physical items—Complainants have not been able to identify
See Apple Memo. at 37-39.8 Nevertheless, the undersigned
finds that the production of physical items,
sufficient evidentiary support for Complainants' representation in the Amended
Complaint that "Masimo Watch" samples could have been made available. 9

Apple's motion relies heavily on the precedent in *Certain Concealed Cabinet Hinges*, where the Commission terminated an investigation based on a Complainant's false and materially misleading representations regarding its domestic industry. *See* Inv. No. 337-TA-289, Comm'n Op., 12 ITRD 1841, 1990 WL 10608981, at \*1-8 (Jan. 8, 1990); Apple Memo. at 39-40. The Commission determined that sanctions were warranted in *Concealed Cabinet Hinges* where, *inter alia*, the "domestic industry allegations were made with conflicting personal knowledge on the part of both [complainant] and counsel for complainant," complainant gave conflicting testimony regarding whether domestic industry products were assembled in the

<sup>&</sup>lt;sup>8</sup> Apple characterizes Complainants' behavior as "discovery misconduct," but the present motion does not seek discovery sanctions. *See supra* n.3.

<sup>&</sup>lt;sup>9</sup> The undersigned has made no determination as to what a preponderance of the evidence will show with respect to whether a "Masimo Watch" satisfying the technical prong of the domestic industry requirement for any asserted patent existed at the relevant time. The relevant issue on this motion is only whether there is sufficient evidentiary support for Masimo's allegations such that sanctions are not warranted.

CONFIDENTIAL INFORMATION REDACTED

#### CONTAINS CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

United States, and complainant "admitted to performing little or no prefiling inquiry" regarding assembly in the United States." *Id.* at \*5. As discussed above, Apple has not made a similar showing with respect to the disputed statements in the Amended Complaint. While there is mixed evidence regarding the "Masimo Watch," Apple has not shown that Complainants' representations in the Amended Complaint lack evidentiary support, and accordingly, no sanctions are warranted.

#### V. CONCLUSION

SO ORDERED.

For the reasons discussed above, Apple's motion for sanctions (1276-012) is hereby DENIED.

This order has been issued with a confidential designation. Within seven days of the date of this document, the parties shall submit a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit a single proposed public version of this order with any proposed redactions in the manner specified by Ground Rule 1.9. To the extent possible, the proposed redacting should be made electronically, in a PDF of the issued order, using the "Redact Tool" within Adobe Acrobat, wherein the proposed redactions are submitted as "marked" but not yet "applied." The submission shall be made by email to Bhattacharyya337@usitc.gov and need not be filed with the Commission Secretary.

Monica Bhattacharyya

Administrative Law Judge

## CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

Certificate of Service – Page 1

#### **CONFIDENTIAL CERTIFICATE OF SERVICE**

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served upon the following parties as indicated, on **April 28, 2022**.

Lisa R. Barton, Secretary U.S. International Trade Commission 500 E Street, SW, Room 112 Washington, DC 20436

## On Behalf of Complainants Masimo Corporation and Cercacor Laboratories, Inc.:

Joseph R. Re, Esq.  KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 Main Street Fourteenth Floor Irvine, CA 92614 joe.re@knobbe.com  On Behalf of Respondent Apple Inc.:	<ul> <li>□ Via Hand Delivery</li> <li>□ Via Express Delivery</li> <li>□ Via First Class Mail</li> <li>⋈ Other: Email Notification of Availability for Download</li> </ul>
Sarah R. Frazier, Esq.  WILMER CUTLER PICKERING HALE AND DORR LLP 60 State Street Boston, MA 02109 Sarah.Frazier@wilmerhale.com	<ul> <li>□ Via Hand Delivery</li> <li>□ Via Express Delivery</li> <li>□ Via First Class Mail</li> <li>⋈ Other: Service to Be</li> <li>Completed by Complainants</li> </ul>

# **EXHIBIT 3**Confidential Business Information

## UNITED STATES INTERNATIONAL TRADE COMMISSION

In the Matter of Investigation No.

CERTAIN LIGHT-BASED PHYSIOLOGICAL 337-TA-1276

MEASUREMENT DEVICES AND COMPONENTS

THEREOF

## REVISED AND CORRECTED TRANSCRIPT OPEN/CLOSED SESSIONS

Pages: 1 through 282

Place: Washington, D.C.

Date: June 6, 2022

#### HERITAGE REPORTING CORPORATION

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Washington, D.C. 20005
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- 1 than argue about their admissibility in advance.
- JUDGE BHATTACHARYYA: That's fine, if that's the
- 3 procedure -- that's fine.
- 4 MR. RE: Yes. There are four objected to
- 5 exhibits that I do want to introduce despite the objection,
- 6 and I'm ready to respond if argument is required.
- 7 JUDGE BHATTACHARYYA: Okay.
- 8 MR. RE: Thank you.
- 9 JUDGE BHATTACHARYYA: Welcome, Mr. Kiani. Do you
- 10 understand that you're under an obligation to tell the truth
- 11 here today?
- 12 THE WITNESS: Yes, Your Honor.
- JOSEPH KIANI,
- having been first duly sworn and/or affirmed
- on his oath, was thereafter examined and testified as
- 16 follows:
- 17 DIRECT EXAMINATION
- 18 BY MR. RE:
- 19 Q. Good morning, Mr. Kiani. For the record, could
- 20 you please give your full name and spell your name?
- 21 A. Yes. My name is Massi Joseph E. Kiani,
- 22 M-A-S-S-I, Joseph, E, and K-I-A-N-I.
- Q. What are your current positions?
- 24 A. I am chairman and CEO of Masimo and Cercacor.
- Q. For how long have you been the CEO of Masimo?

- 1 20 different articles written about it, and put on the news
- 2 about the availability of a medical-grade Masimo SET pulse
- 3 oximeter for the first time available on these kinds of
- 4 devices.
- 5 Q. And if I could show you Complainants' Exhibit
- 6 1512, could you explain for the record what is this exhibit
- 7 showing?
- 8 A. Yeah, I think this is just some of the -- kind of
- 9 like the cutouts of some of these articles that had come
- 10 out, 21 articles that had come out as of January 10th, 2013.
- 11 O. And did Apple take notice of the notoriety you
- 12 were receiving with your consumer product for use with the
- 13 iPhone?
- 14 A. Yes. Within two to three months they contacted
- 15 us, and they said you guys are the platinum of noninvasive
- 16 monitoring, we want you to come down to Cupertino, we want
- 17 to learn more, we'll sign your NDA, we want to work with you
- 18 to integrate your technology into our products.
- 19 Q. Did you have such a meeting?
- 20 A. Yes, we did. I was personally there.
- 21 Q. And did Apple send you an agenda for the meeting?
- 22 A. Yes, they did.
- Q. I'd like to show you an exhibit, which Apple has
- 24 objected to, so I'm alerting Mr. Mueller, it's Exhibit 1539.
- 25 Could you --

- 1 OPEN SESSION
- 2 BY MR. RE:
- 3 Q. When did you become interested in a
- 4 wrist-wearable pulse oximeter?
- 5 A. Actually from the very beginning. When I started
- 6 Masimo, I hoped to one day build a wrist-worn pulse
- 7 oximeter, because I hoped to one day take the product out of
- 8 the hospital into home for sleep analysis, for detecting
- 9 babies that are about to die from sudden infant death
- 10 syndrome, to even taking it to the gym, take it to people
- 11 who are exercising. So that's been something since
- 12 practically 1990, 1991 that I was --
- 13 Q. And why weren't you able to do it back then and
- 14 just go on to the wrist?
- 15 A. As I mentioned, the power. Our technology, we do
- 16 so much signal processing with the adaptive filter, it used
- 17 to take a very sophisticated sharp chip from analog devices
- 18 that consumed about 3,000 milliwatts. Fortunately over time
- 19 these chips have gotten better and smaller and more power.
- 20 So, look, if I wanted to do conventional pulse
- 21 oximeter, I could have made a wrist-worn device 30 years
- 22 ago, but to make something that works accurately, reliably,
- 23 continuously, it needed to be Masimo SET or very close, and
- 24 that's what we were waiting for. And eventually we did get
- 25 the power down to do that.

1	С	O	Ν	F	Ι	D	Е	Ν	Т	Ι	Α	L	S	Ε	S	S	I	Ο	Ν	
---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	--

- JUDGE BHATTACHARYYA: We're moving to the Masimo
- 4 confidential record.
- 5 Can Ms. Frazier confirm that no unauthorized
- 6 persons are presents?
- 7 MR. MUELLER: She just confirmed. We can make
- 8 that confirmation.
- 9 JUDGE BHATTACHARYYA: Mr. Re, are you comfortable
- 10 going forward?
- 11 MR. RE: I, of course, take Ms. Frazier's word
- 12 for it. Thank you.
- JUDGE BHATTACHARYYA: Go ahead.
- MR. MUELLER: Thank you, Your Honor.
- 15 BY MR. MUELLER:

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- 1 BY MR. RE:
- Q. Okay. Does the Radius PPG require Root?
- 3 A. No, it does not. It can work with any Bluetooth
- 4 device.
- 5 O. And what are Bluetooth devices that work with
- 6 Radius PPG?
- 7 A. Well, a whole host of them, from the iOS phones,
- 8 to the Android phones, to the tablets that you can buy. So,
- 9 yeah, any of them.
- 10 Q. Okay. One other thing. You had early in your
- 11 testimony, I think it might have been before the lunch
- 12 break, you and Mr. Mueller were having a debate about
- 13 evidence of whether, you know, Apple could have gotten ideas
- 14 from Masimo. Do you remember that?
- 15 A. I do.
- 16 Q. And you kept saying I don't have any direct
- 17 evidence, it's only circumstantial, right?
- 18 A. Yes.
- 19 Q. What did you mean by that?
- 20 A. Well, no other company except the one that took
- 21 30 of our engineers, including or CTO, who was an inventor
- 22 of the three patents in this case came up with a
- 23 convex-shaped sensor for monitoring pulse ox.
- 24 So that's one of the evidence as I think leads me
- 25 to believe that they took it from us. And also other

- 1 companies that do copy Apple, of course they are going to
- 2 copy Apple, and we're going to have more people with these
- 3 convex-based sensors. Before then, nobody else had it.
- 4 Q. And Mr. Mueller also asked you about that meeting
- 5 that occurred in May 3rd, 2013. Do you remember that?
- 6 A. Yes.
- 7 O. And --
- 8 MR. MUELLER: I'm sorry to interrupt. If we're
- 9 going to get into that, if we could go on the Apple-Masimo
- 10 confidential record.
- 11 MR. RE: I won't get into the content of the
- 12 meeting. I didn't intend to. I just want to ask one
- 13 question.
- Q. Was there any agreement signed prior to the
- 15 meeting at Apple in May of 2013?
- 16 A. Yes. Apple asked us to tell them confidential
- information, a product roadmap, how and why it worked, so we
- 18 insisted on an NDA, and we had a nondisclosure agreement
- 19 between us for that meeting.
- 20 Q. And was confidential information exchanged
- 21 pursuant to that signed NDA?
- 22 A. Yes.
- MR. RE: I have no further questions, Your Honor.
- MR. MUELLER: Just briefly, Your Honor.
- MR. RE: Oh, is there two rounds for every

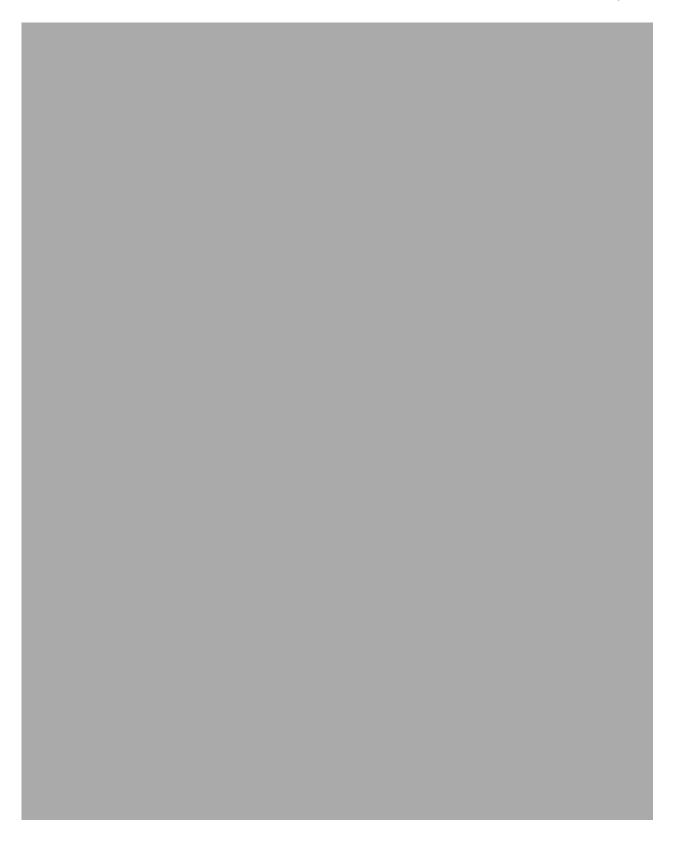
- 1 MS. SWAROOP: Your Honor, Complainants' next
- 2 witness will be Mr. Ammar Al-Ali, and Mr. Jensen will be
- 3 conducting that examination.
- 4 MR. MUELLER: Your Honor, Sarah Frazier will be
- 5 conducting the cross-examination.
- 6 JUDGE BHATTACHARYYA: Thank you.
- 7 MR. JENSEN: Good afternoon, Your Honor. This is
- 8 Steve Jensen.
- 9 Mr. Al-Ali, are you comfortable and do you have
- 10 your book?
- 11 THE WITNESS: Yes. Good afternoon.
- MR. JENSEN: May we begin, Your Honor?
- 13 JUDGE BHATTACHARYYA: I'll swear in the witness
- 14 first before we proceed further.
- Mr. Al-Ali, did I pronounce it right?
- 16 THE WITNESS: That's correct.
- 17 JUDGE BHATTACHARYYA: Welcome. Thank you for
- 18 coming. Do you understand you're under an obligation to
- 19 tell the truth here today?
- 20 THE WITNESS: I do.
- 21 AMMAR AL-ALI,
- 22 having been first duly sworn and/or affirmed
- 23 on his oath, was thereafter examined and testified as
- 24 follows:
- JUDGE BHATTACHARYYA: Thank you.

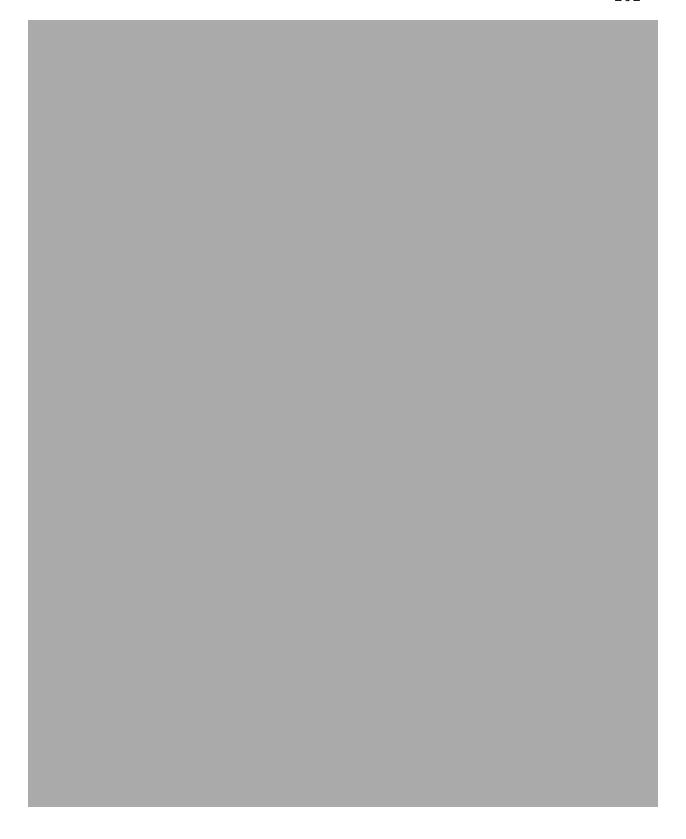
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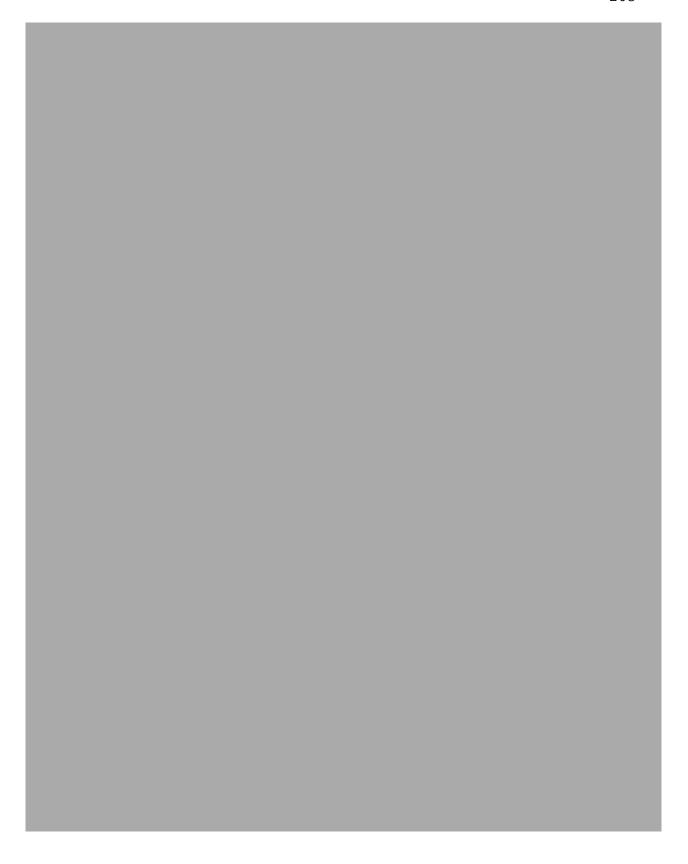
#### 1 DIRECT EXAMINATION

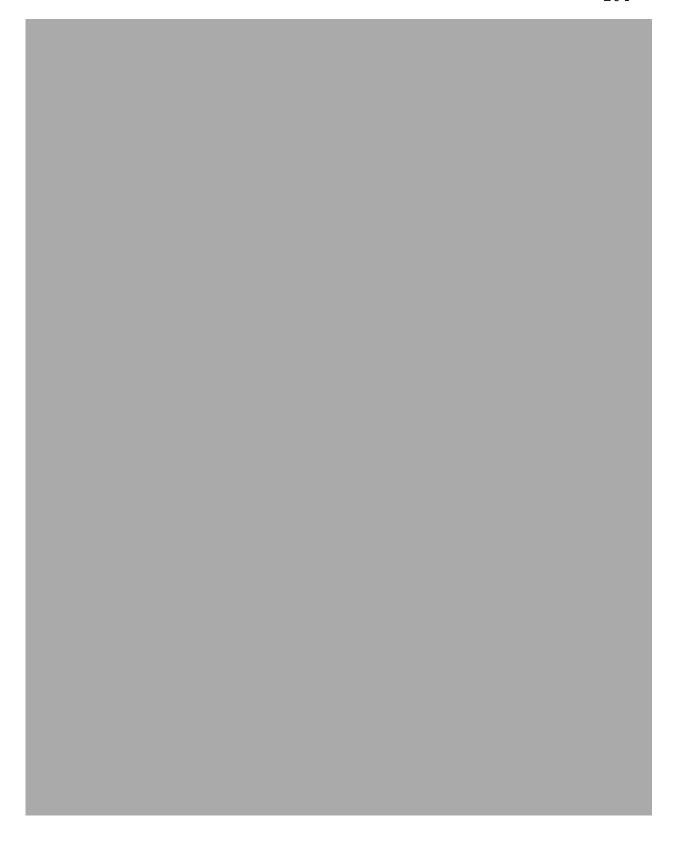
- 2 BY MR. JENSEN:
- 3 O. Mr. Al-Ali, could you please state and spell your
- 4 name for the record?
- 5 A. Ammar Al-Ali, A-M-M-A-R, A-L hyphen A-L-I.
- 6 Q. And who is your current employer?
- 7 A. Masimo Corporation.
- 8 Q. When did you start at Masimo?
- 9 A. I started April 1995.
- 10 Q. Could you just briefly explain your job history
- 11 at Masimo since you started?
- 12 A. Yes. I started at Masimo in '95 as a software
- 13 engineer, and then moved from that to manage the engineering
- 14 department. I worked in the early days of '95 to about 2000
- 15 on the Masimo saturation algorithm.
- And then after that our RAD system, which is a
- 17 medical device, and then after that I worked on the rainbow«
- 18 system, and lately I've been working on wearable
- 19 technologies.
- 20 O. And what are your current responsibilities at
- 21 Masimo?
- 22 A. Right now I oversee the technology development of
- 23 the company.
- 24 O. Okay. And you mentioned wearables in your
- 25 previous answer. Did there come a point in time when from

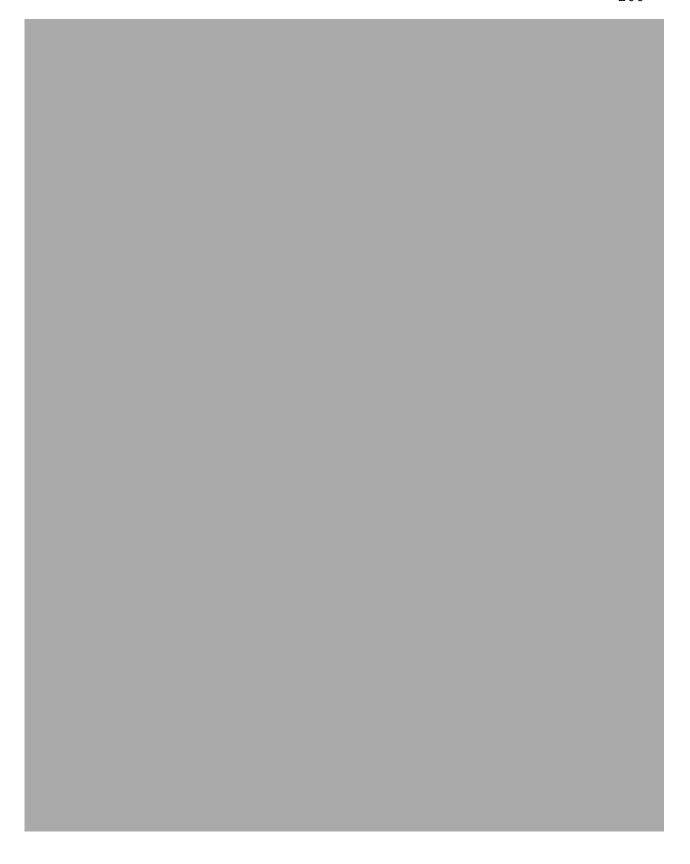
- 1 the subject matter. I gave disclosure to the attorneys to
- 2 actually file the patent.
- Q. Okay. And then you said that things started
- 4 from -- I think you said working more with a team happened a
- 5 little later.
- 6 What started happening then when you picked it
- 7 back up, I think you said?
- 8 A. Oh, in 2019 we put a complete team behind this
- 9 technology. We hired mechanical engineers, electronic
- 10 engineers, and software. So we actually started making the
- 11 sensor and trying to optimize its performance.
- 12 O. And when did Masimo have its own wrist pulse
- 13 oximeter devices with sensing on the wrist?
- 14 A. This would be late 2019.
- 15 Q. And could you please on the -- it's on the stand
- 16 that's behind you -- or someone might have put it next to
- 17 you, please find Complainants' physical exhibit 22. It's
- 18 either there or it's on the cart.
- 19 A. Oh, it's on the cart.
- 20 Q. Number 22.
- 21 A. I found it.
- 22 Q. Okay. Do you recognize Complainants' Exhibit 22?
- 23 A. Yes. It's one of our early sensors.
- 24 Q. Can you show us just on your camera there, not on
- 25 the ELMO, but just on the camera what you're holding?

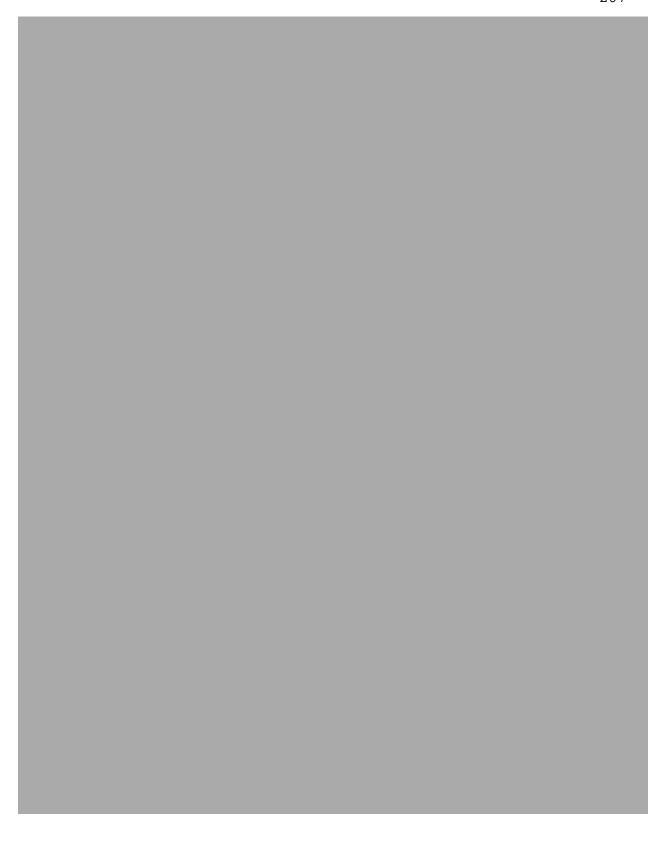


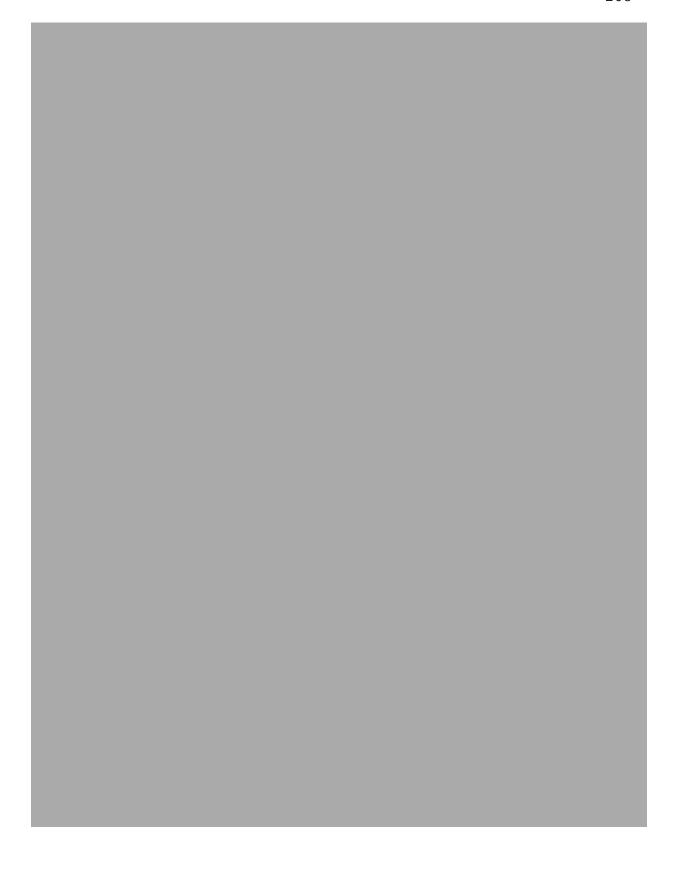












Τ	CERTIFICATE
2	TITLE: CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES
3	AND COMPONENTS THEREOF
4	INVESTIGATION NO.: 337-TA-1276
5	HEARING DATE: June 6, 2022
6	LOCATION: Washington, D.C Remote
7	NATURE OF HEARING: Evidentiary Hearing
8	I hereby certify that the foregoing/attached transcript is a true, correct and complete record of the
9	above-referenced proceedings of the U.S. International Trade Commission.
LO	Date: June 29, 2022 Signed: ( ( )
11	ss// Showe Johnson
L2	Signature of the Contractor or the Authorized Contractor's Representative
L3	
L4	I hereby certify that I am not the court reporter and that I have proofread the above-referenced transcript of
L5	the proceedings of the U.S. International Trade Commission against the aforementioned court reporter's notes and
L6	recordings for accuracy in transcription in the spelling, hyphenation, punctuation and speaker identification and did
L7	not make any changes of a substantive nature. The foregoing/attached transcript is a true, correct and
L8	complete transcription of the proceedings. Signed:
L9	ss// Raymond G. Brynteson
20	V
21	I hereby certify that I reported the above-referenced proceedings of the U.S. International Trade
22	Commission and caused to be prepared from my record media and notes of the proceedings a true, correct and complete
23	verbatim recording of the proceedings. Signed:
24	ss// Linda Kenkade

# **EXHIBIT 4**Confidential Business Information

# UNITED STATES INTERNATIONAL TRADE COMMISSION

In the Matter of Investigation No.

CERTAIN LIGHT-BASED PHYSIOLOGICAL 337-TA-1276

MEASUREMENT DEVICES AND COMPONENTS

THEREOF

#### OPEN/CLOSED SESSIONS

Pages: 283 through 596

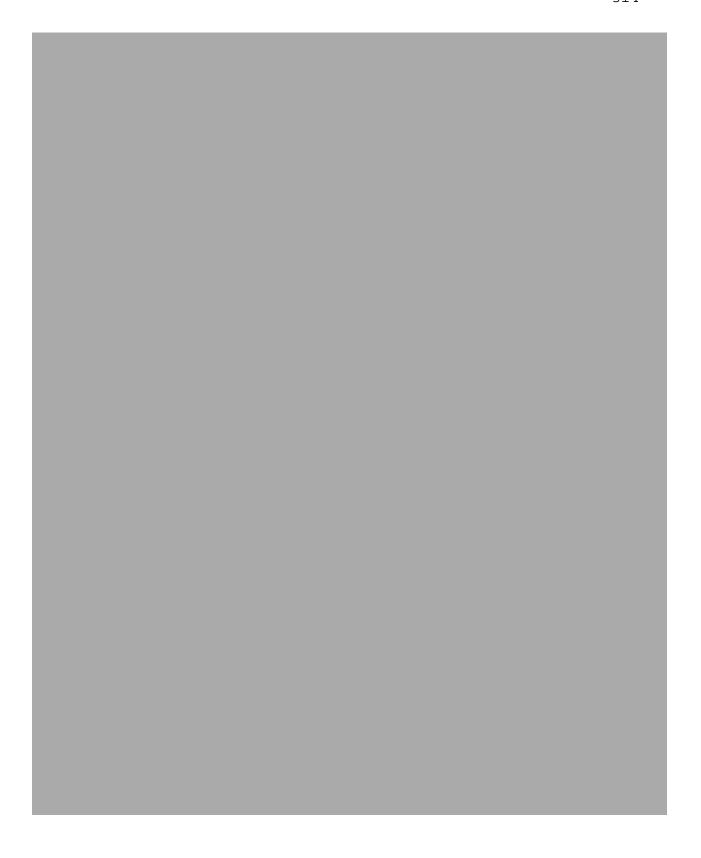
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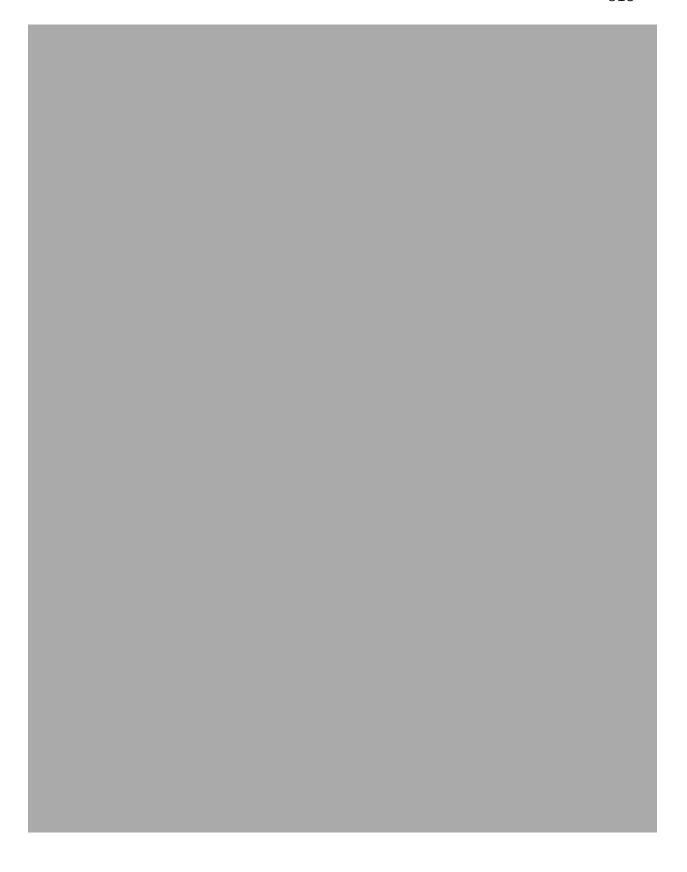
Date: June 7, 2022

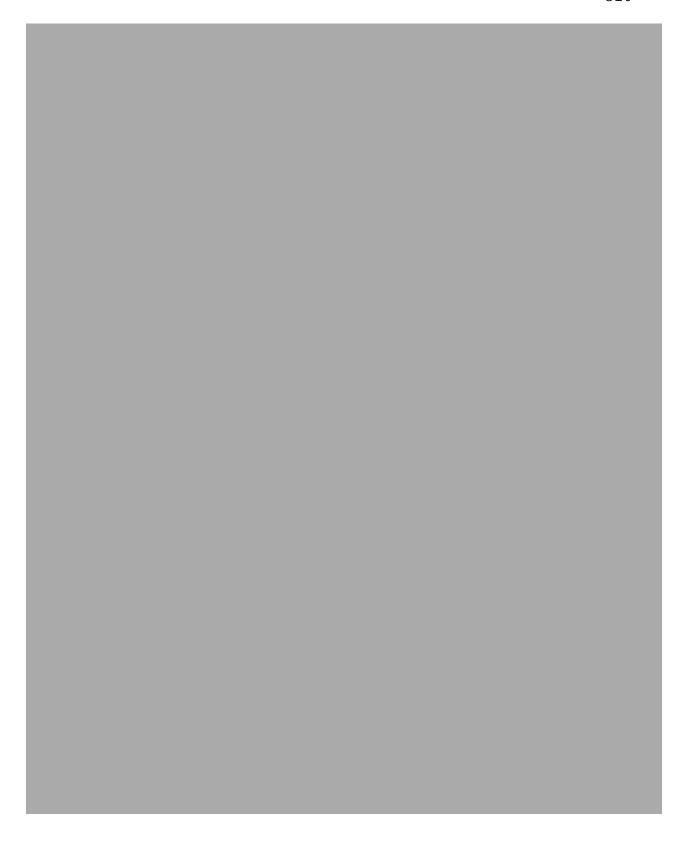
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9 DIRECT EXAMINATION 10 BY MR. JENSEN: Q. Good morning, Mr. Al-Ali. Welcome back. Can you 11 12 hear us okay in there? 13 A. Yes, I can. Thank you.







1	OPEN SESSION
2	MS. SWAROOP: Your Honor, for our next witness,
3	Complainants call Bilal Muhsin. We're just getting him set
4	up in the witness room.
5	JUDGE BHATTACHARYYA: Okay.
6	MR. MUELLER: Your Honor, I'll be conducting this
7	cross-examination.
8	JUDGE BHATTACHARYYA: Thank you.
9	MR. MUELLER: Are we back on the public record,
10	Your Honor?
11	JUDGE BHATTACHARYYA: Yes, we are.
12	MR. MUELLER: Okay. Thank you, Your Honor.
13	MS. SWAROOP: Our witness is ready.
14	Good morning, Mr. Muhsin.
15	JUDGE BHATTACHARYYA: Good morning. Could you
16	help me pronounce your name again?
17	THE WITNESS: Bilal.
18	JUDGE BHATTACHARYYA: And the last name?
19	THE WITNESS: Muhsin.

- JUDGE BHATTACHARYYA: Okay. Mr. Muhsin, thank
- 21 you for coming here today. Do you understand you're under
- 22 an obligation to tell the truth in your testimony?
- THE WITNESS: I do.
- 24 BILAL MUHSIN,
- 25 having been first duly sworn and/or affirmed

Case: 24-1285 Document: 25-3 Page: 50 Filed: 01/10/2024

- 1 on his oath, was thereafter examined and testified as
- 2 follows:
- 3 DIRECT EXAMINATION
- 4 BY MS. SWAROOP:
- 5 Q. Good morning, Mr. Muhsin.
- 6 A. Good morning.
- 7 Q. Could you please describe your current
- 8 employment?
- 9 A. I'm the Chief Operating Officer at Masimo.
- 10 Q. How long have you held that position?
- 11 A. Since 2019.
- 12 O. What are your responsibilities as the Chief
- 13 Operating Officer at Masimo?
- 14 A. I oversee R&D, regulatory, quality, operations,
- 15 and commercial for Masimo, and clinical affairs as well.
- 16 Q. Mr. Muhsin, what is the Masimo Watch project?
- 17 A. It is a project that formally started in 2019.
- 18 It's about a design of a wrist sensor that's able to
- 19 calculate pulse oximetry, the SpO2 reading, and has other
- 20 functionalities that a watch would have.
- 21 Q. What is your role in the Masimo Watch project?
- 22 A. I'm no longer a hands-on engineer, but I do
- 23 oversee the entire R&D development, the operation side, and
- 24 the commercialization side of the product.
- 25 Q. You mentioned that the Masimo Watch project

MAS-ADD-070

- 1 industrial design were not manufactured until December of
- 2 2021, correct?
- 3 A. November, December time frame.
- 4 Q. Now we can take those images down.
- 5 The complaint actually included a declaration
- 6 from you; is that right, sir?
- 7 A. Yes, it did.
- 8 Q. And because we're on the public record I'm not
- 9 going to pull up the actual content of the declaration, but
- 10 that declaration included some computer-assisted design
- 11 drawings, right, sir?
- 12 A. It included some drawings, yes, CAD drawings.
- 13 Q. And those are called CAD drawings,
- 14 computer-assisted design, correct?
- 15 A. Yes.
- 16 Q. And you don't know when those were created,
- 17 right?
- 18 A. Meaning?
- 19 Q. You don't know when the CAD drawings were
- 20 created, correct?
- 21 A. Prior to me submitting that, yes, they were. I
- 22 mean, they were created prior to my submission, yes.
- Q. But you don't know exactly when.
- 24 A. No.
- Q. And those CAD drawings did not correspond to an

- 1 actual physical device that existed at that time, correct?
- 2 A. A design did correspond to a physical.
- 3 O. Sir, you did not put in in your complaint a
- 4 photograph of an actual physical device in existence at that
- 5 time, did you.
- 6 A. That is correct. I did not put in a photograph.
- 7 Q. Now if a device actually existed at that time
- 8 that matched the CAD drawing, nothing would have stopped you
- 9 from taking a photograph of it, right?
- 10 A. I testified to this in my deposition that I wore
- 11 that same device on my wrist prior to me putting that
- 12 declaration together with that same design.
- 13 Q. And, sir, if you wore it on your wrist, surely
- 14 someone could have taken a photograph of it and attached it
- 15 to the complaint, correct?
- 16 A. It wasn't -- it wasn't -- I didn't make the call
- 17 whether it was a photograph or something else.
- 18 Q. Well, whoever made the call, what was attached to
- 19 the complaint was not what you are testifying to now; it was
- 20 a computer-assisted design drawing, correct?
- 21 A. In the complaint it was. And when we walked
- 22 through the samples during my deposition, I walked you
- 23 through --
- Q. Sir, please, just stay with my question.
- 25 Ms. Swaroop will have a chance to ask you questions later

1 OPEN SESSION

- 3 MS. SWAROOP: Are we on the public record now?
- 4 JUDGE BHATTACHARYYA: Yes, we are.
- 5 MS. SWAROOP: Thank you, Your Honor.
- 6 Mr. Scruggs, do you have a binder with you there
- 7 in the room?
- 8 THE WITNESS: Yes, I have a binder.
- 9 MS. SWAROOP: We are ready to proceed. Before we
- 10 begin, you're a little soft-spoken, so I would just ask that
- 11 you try and speak as close to the mic as you can.
- 12 THE WITNESS: Sounds good.
- JUDGE BHATTACHARYYA: Welcome, Mr. Scruggs. Do
- 14 you understand that you are under an obligation to tell the
- 15 truth here today?
- 16 THE WITNESS: Yes, I do.
- 17 STEPHEN SCRUGGS,
- 18 having been first duly sworn and/or affirmed
- 19 on his oath, was thereafter examined and testified as
- 20 follows:
- JUDGE BHATTACHARYYA: You may proceed, counsel.
- 22 DIRECT EXAMINATION
- 23 BY MS. SWAROOP:
- 24 Q. Good morning, Mr. Scruggs. Could you please
- 25 state and spell your last name for the record?

Τ	CERTIFICATE
2	TITLE: CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES
3	AND COMPONENTS THEREOF
4	INVESTIGATION NO.: 337-TA-1276
5	HEARING DATE: June 7, 2022
6	LOCATION: Washington, D.C Remote
7	NATURE OF HEARING: Evidentiary Hearing
8	I hereby certify that the foregoing/attached transcript is a true, correct and complete record of the
9	above-referenced proceedings of the U.S. International Trade Commission.
LO	Date: June 7, 2022 Signed: ()
L1	ss// Denue object
L2	Signature of the Contractor or the Authorized Contractor's Representative
L3	Representative
L4	I hereby certify that I am not the court reporter and that I have proofread the above-referenced transcript of
L5	the proceedings of the U.S. International Trade Commission against the aforementioned court reporter's notes and
L6	recordings for accuracy in transcription in the spelling, hyphenation, punctuation and speaker identification and did
L7	not make any changes of a substantive nature. The foregoing/attached transcript is a true, correct and
L8	complete transcription of the proceedings. Signed:
L9	ss// Raymond G. Brynteson
20	
	I hereby certify that I reported the
21	above-referenced proceedings of the U.S. International Trade Commission and caused to be prepared from my record media
22	and notes of the proceedings a true, correct and complete verbatim recording of the proceedings.
23	Signed:
24	ss// Linda Kenkade

## **EXHIBIT 5**

Page: 63 Filed: 01/10/2024 Case: 24-1285 Document: 25-3

CX-0252

### Page Vault

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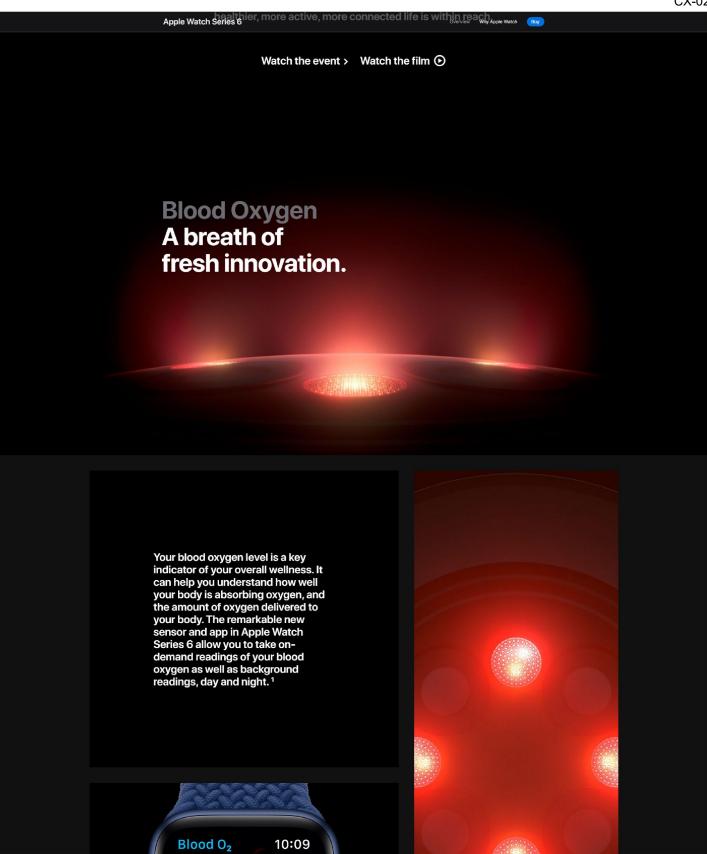
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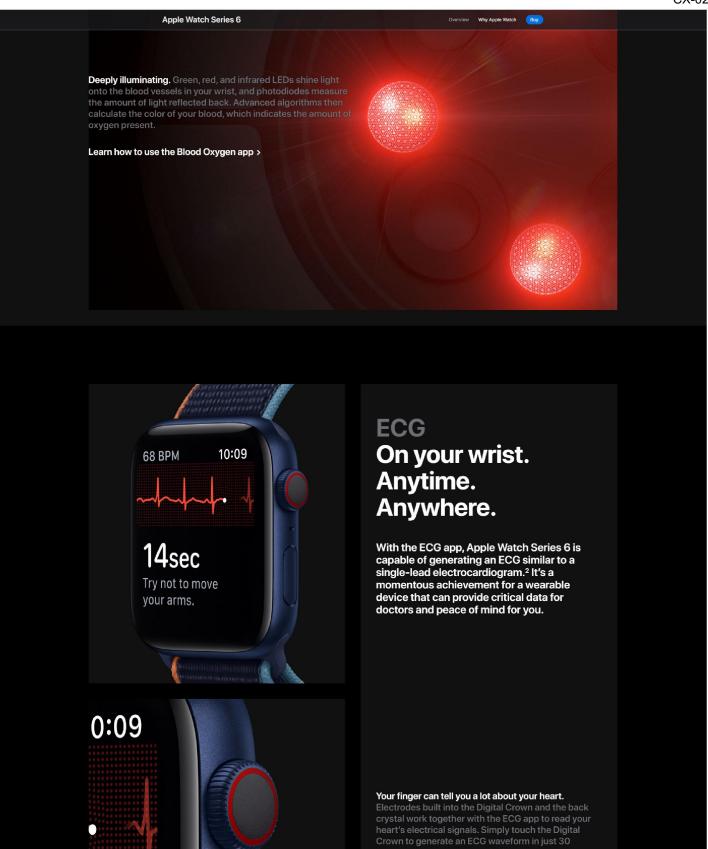
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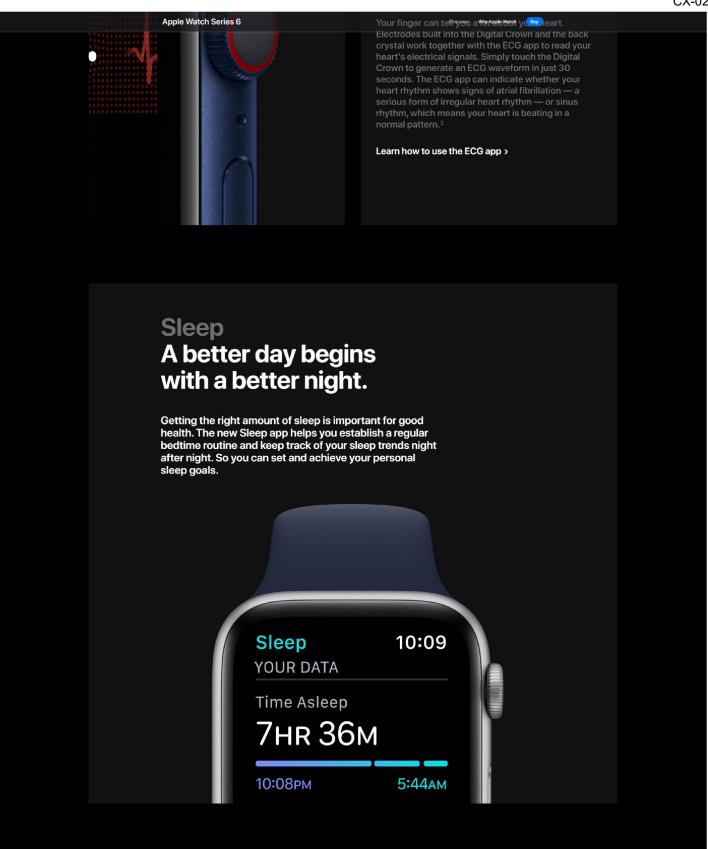
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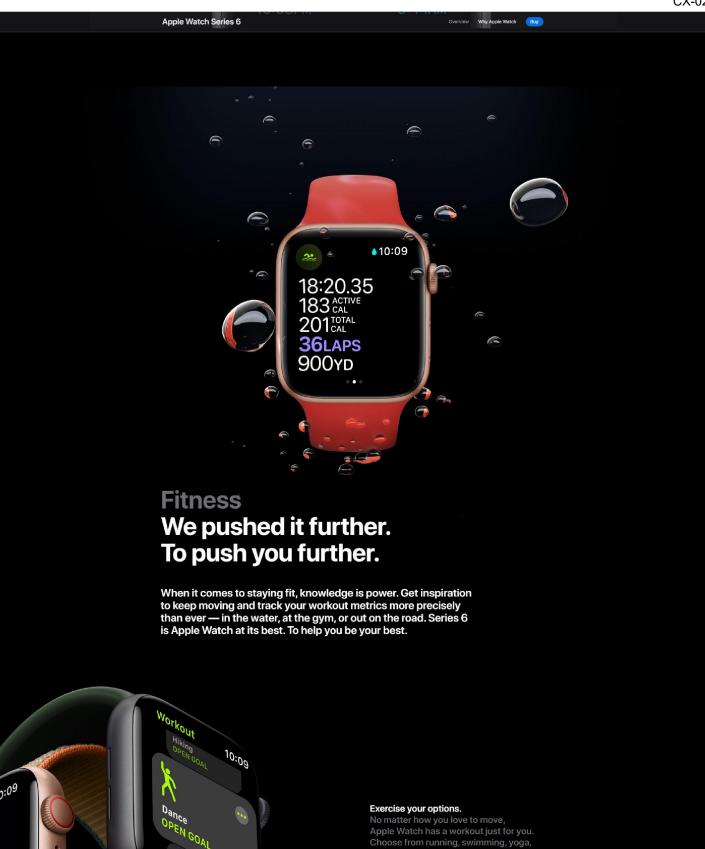
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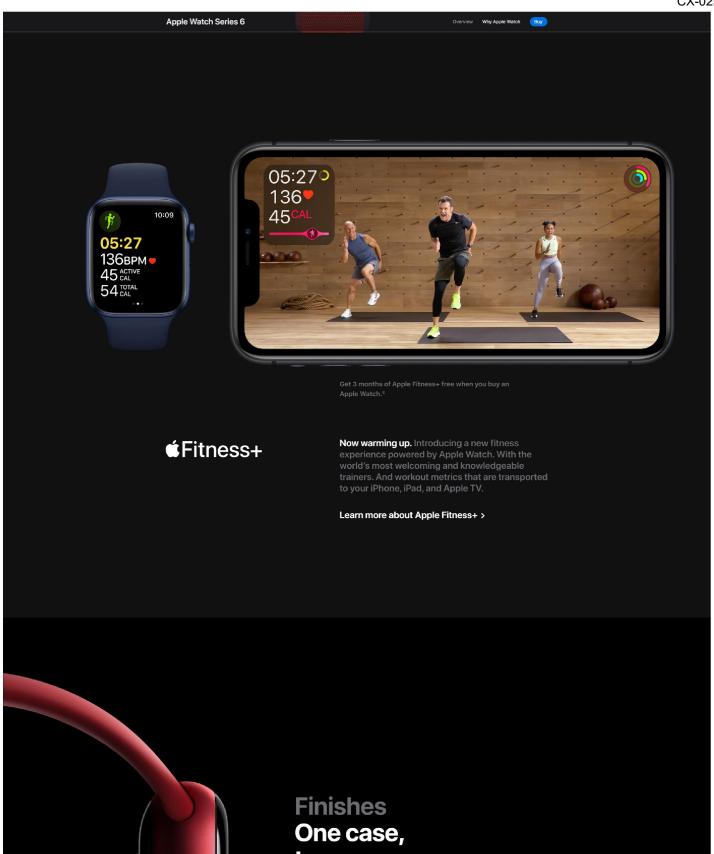


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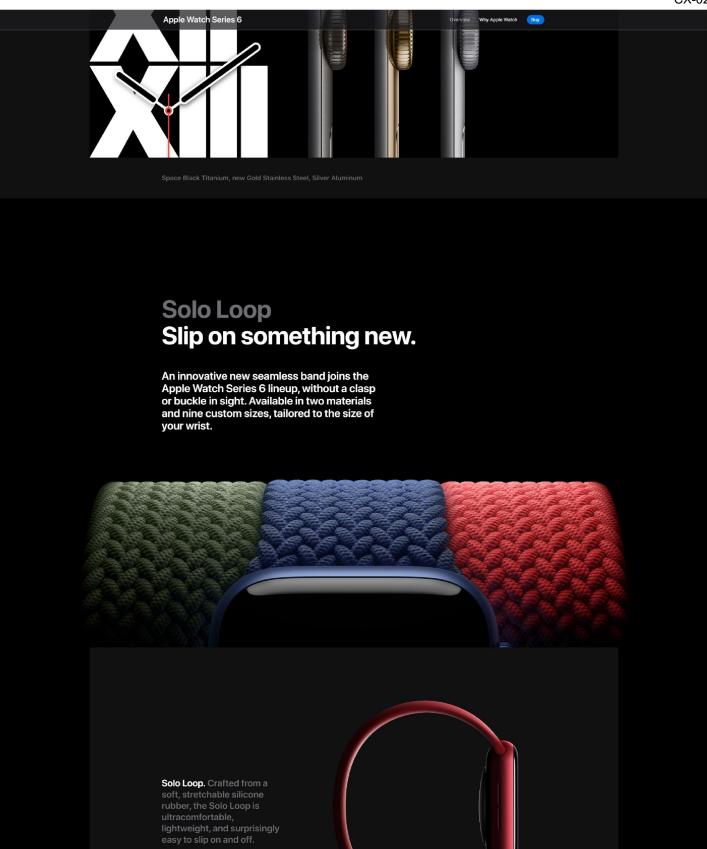
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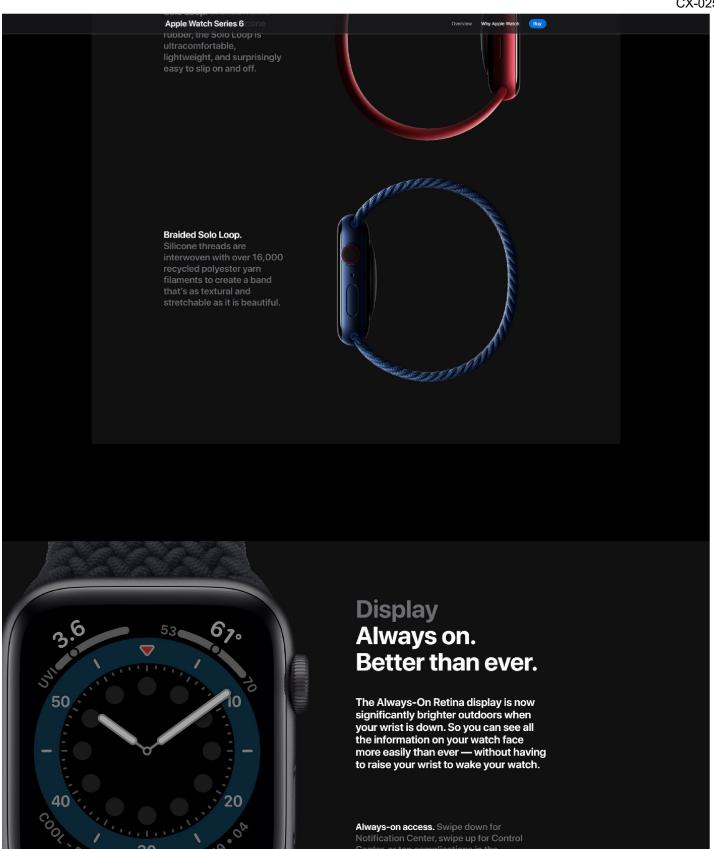
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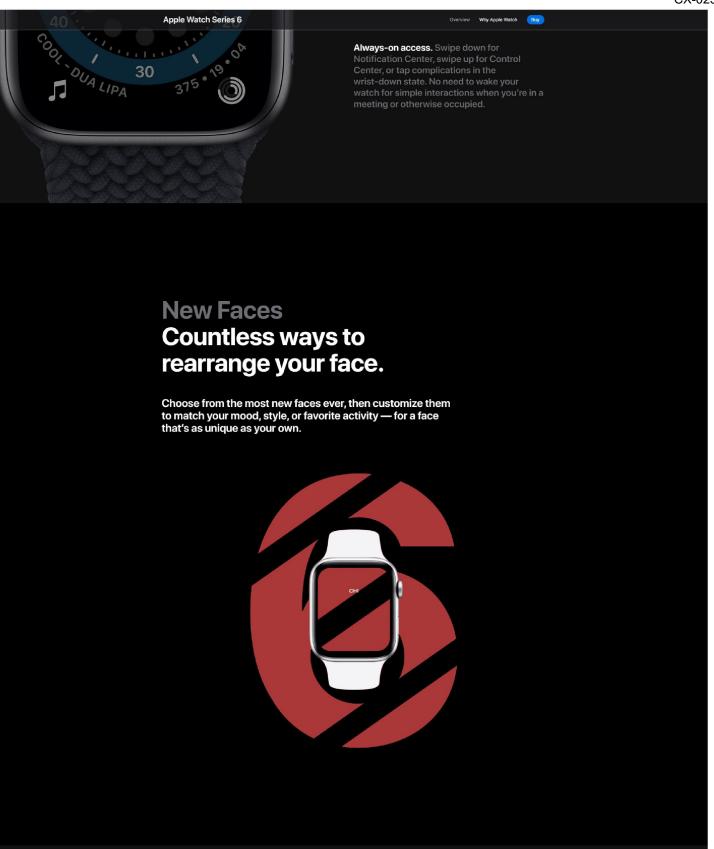
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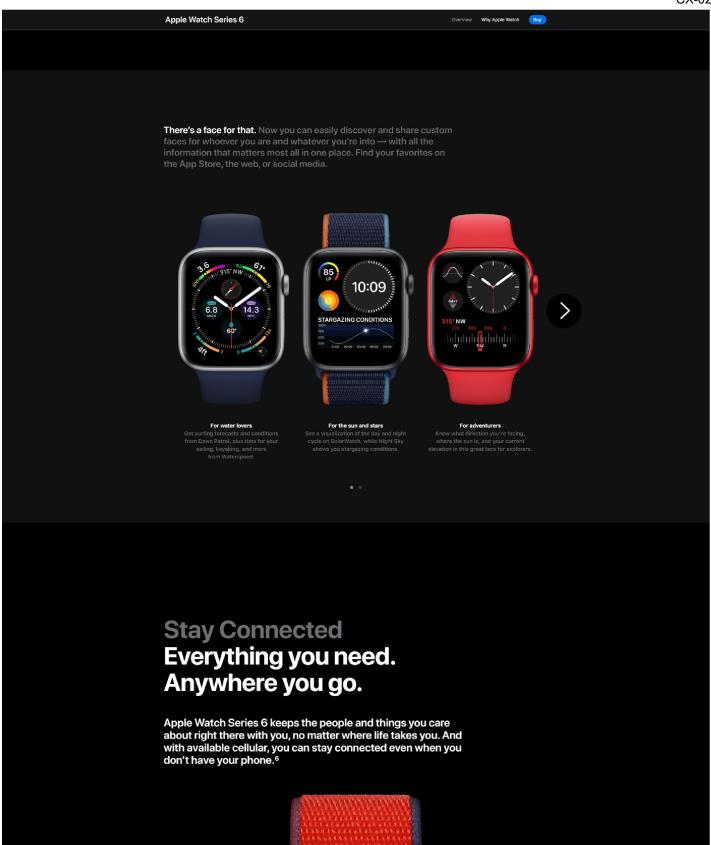
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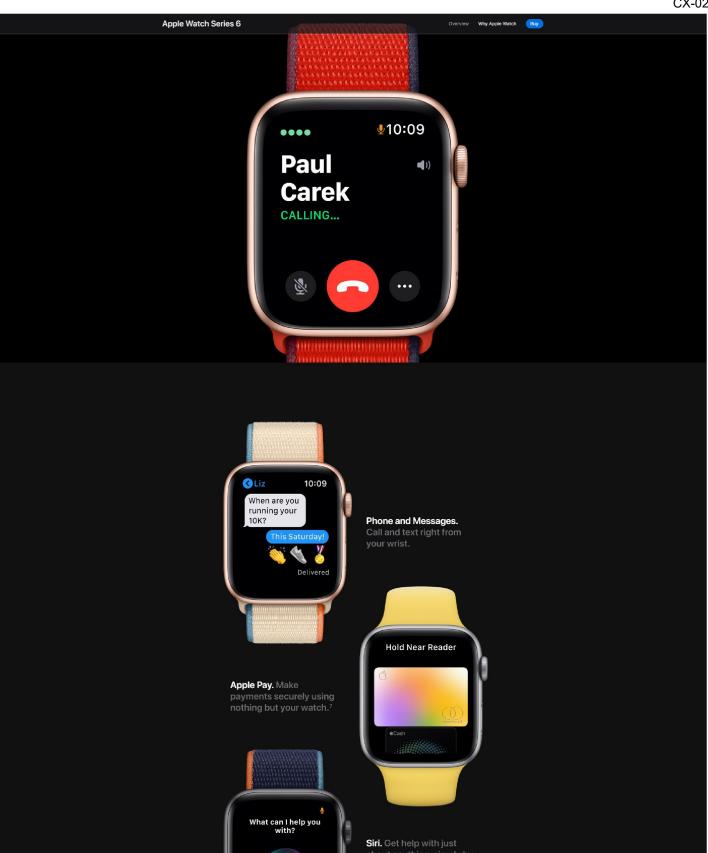
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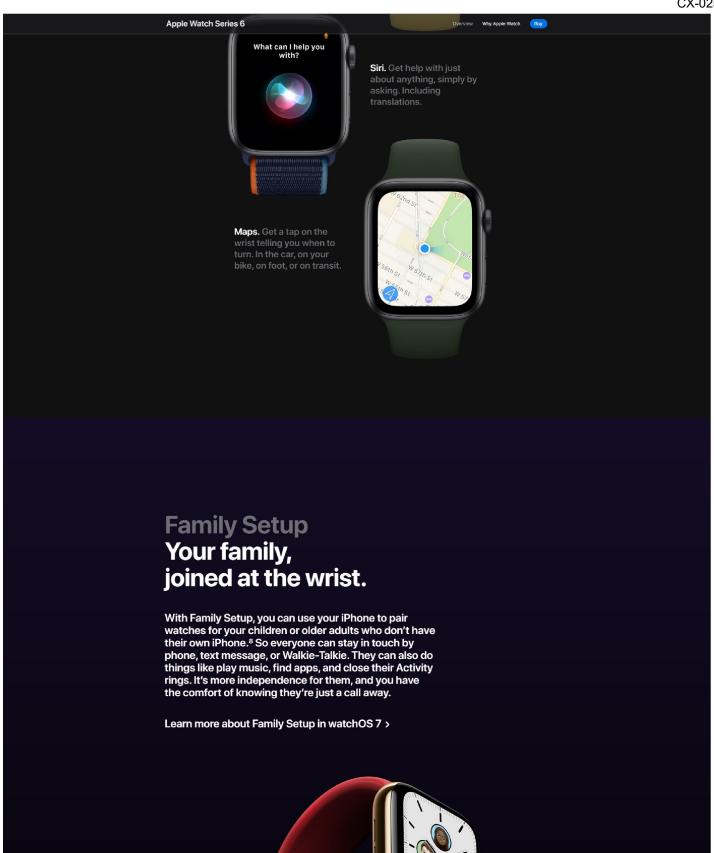
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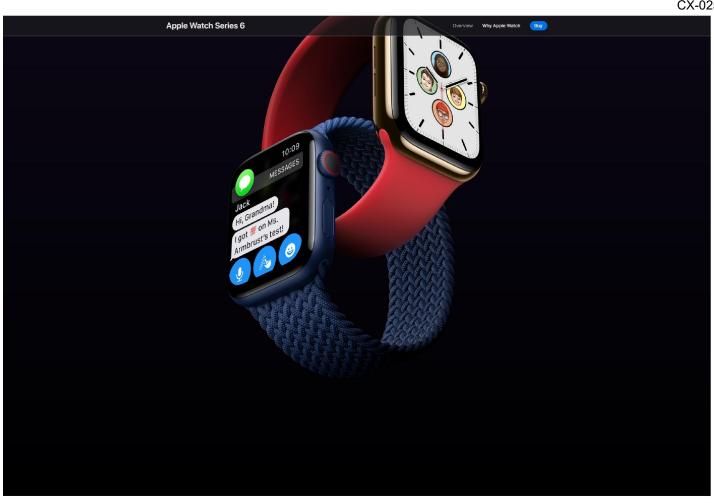


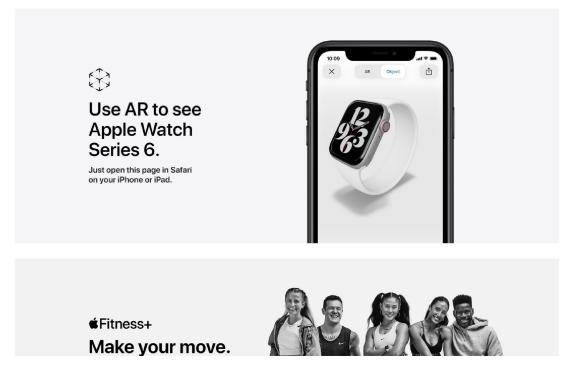
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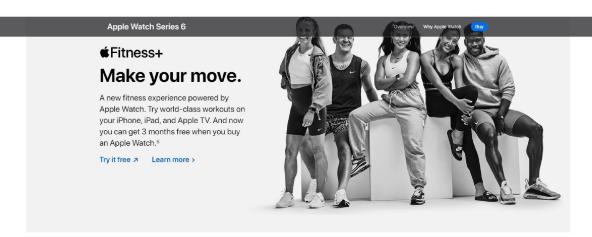
Case: 24-1285 Document: 25-3 Page: 80 Filed: 01/10/2024

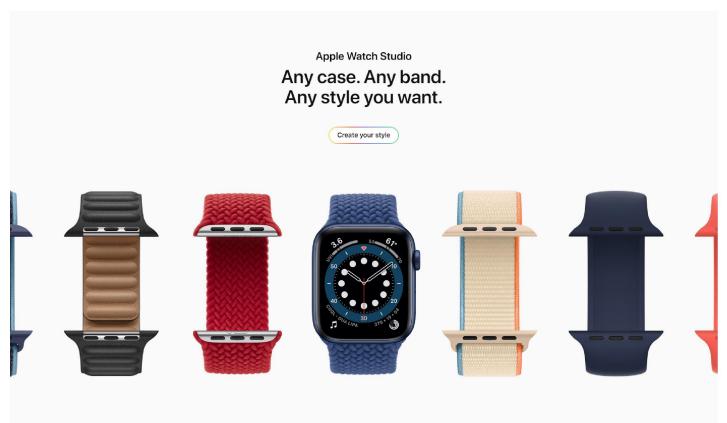
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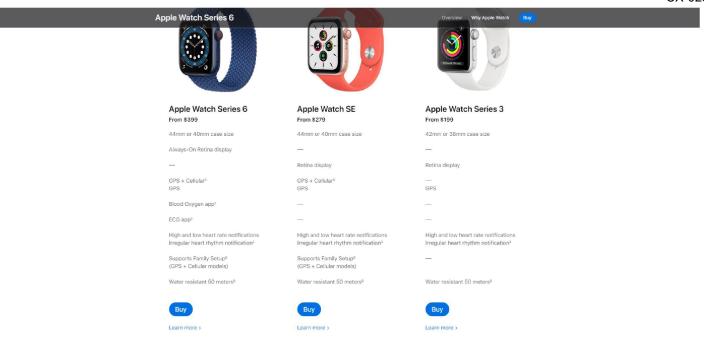


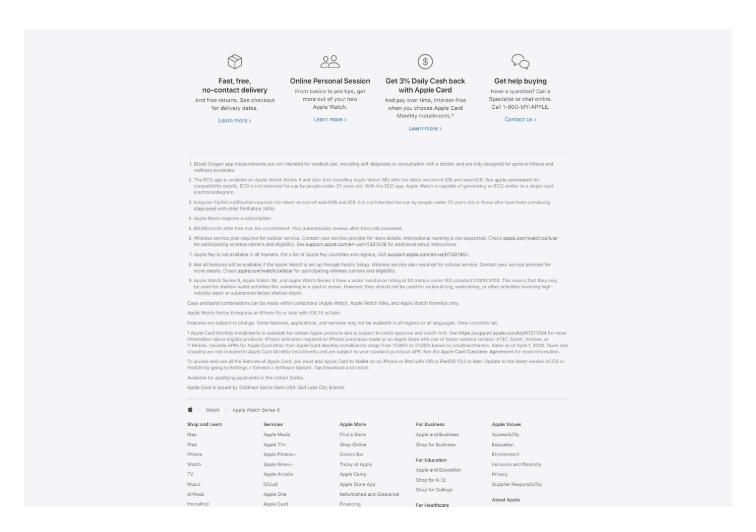


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Page 18 of 20 MASITC\_00918325

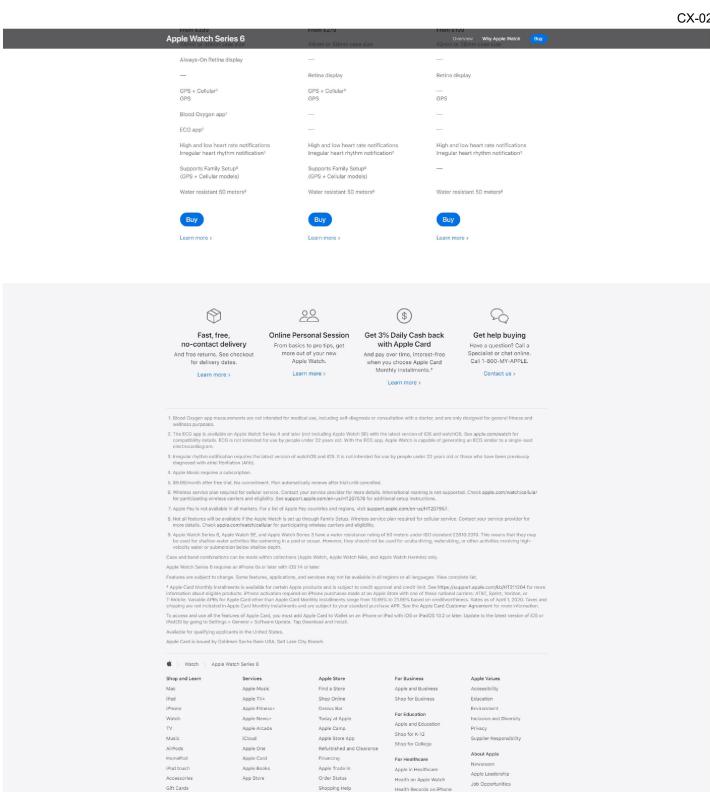
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## **EXHIBIT 6**Confidential Business Information

Case: 24-1285 Document: 25-3 Page: 85 Filed: 01/10/2024 CONFIDENTIAL BUSINESS INFORMATION REDACTED ENTIRELY FROM PAGES MAS-ADD-109 - MAS-ADD-116

### **EXHIBIT 7**

## Confidential Business Information

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## **EXHIBIT 8**Confidential Business Information

Case: 24-1285 Document: 25-3 Page: 87 Filed: 01/10/2024 CONFIDENTIAL BUSINESS INFORMATION REDACTED ENTIRELY FROM PAGES MAS-ADD-132 - MAS-ADD-141

# **EXHIBIT 9**Confidential Business Information

## **EXHIBIT 10**

CX-1287

3/9/22, 5:54 PM

Apple Watch Series 6 delivers breakthrough wellness and fitness capabilities - Apple

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PRESS RELEASE
September 15, 2020

## Apple Watch Series 6 delivers breakthrough wellness and fitness capabilities

Fi 💆 💌 🔗

Featuring a Blood Oxygen sensor and app, new case finishes, and watchOS 7

CX-1287

3/9/22, 5:54 PM

Apple Watch Series 6 delivers breakthrough wellness and fitness capabilities - Apple



Introducing Apple Watch Series 6, featuring a revolutionary Blood Oxygen sensor and app.



Cupertino, California — Apple today announced Apple Watch Series 6, introducing a revolutionary Blood Oxygen feature that offers users even more insight into their overall wellness. Apple Watch Series 6 delivers many notable hardware improvements, including a faster S6 System in Package (SiP) and next-generation always-on altimeter, along with its most colorful lineup yet, featuring a beautiful palette of new case finishes and bands. watchOS 7 brings Family Setup, sleep tracking, automatic handwashing detection, new workout types, and the ability to curate and share watch faces, encouraging customers to be more active, stay connected, and better manage their health in new ways.

"Apple Watch Series 6 completely redefines what a watch can do," said Jeff Williams, Apple's chief operating officer. "With powerful new features, including a Blood Oxygen sensor and app, 1 Apple Watch becomes even more indispensable by providing further insight into overall well-being."



#### Apple Watch Series 6 offers its most colorful collection yet.



#### **Blood Oxygen Sensor and App**

Apple Watch Series 6 expands the health capabilities of previous Apple Watch models with a new feature that conveniently measures the oxygen saturation of

https://www.apple.com/newsroom/2020/09/apple-watch-series-6-delivers-breakthrough-wellness-and-fitness-capabilities/

2/13

Case: 24-1285 Document: 25-3 Page: 91 Filed: 01/10/2024

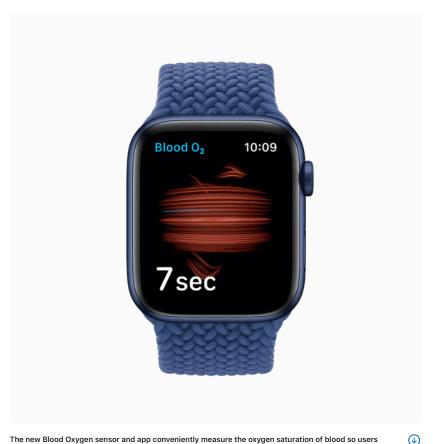
CX-1287

3/9/22, 5:54 PM

Apple Watch Series 6 delivers breakthrough wellness and fitness capabilities - Apple

the user's blood, so they can better understand their overall fitness and wellness. Oxygen saturation, or SpO2, represents the percentage of oxygen being carried by red blood cells from the lungs to the rest of the body, and indicates how well this oxygenated blood is being delivered throughout the body.

To compensate for natural variations in the skin and improve accuracy, the Blood Oxygen sensor employs four clusters of green, red, and infrared LEDs, along with the four photodiodes on the back crystal of Apple Watch, to measure light reflected back from blood. Apple Watch then uses an advanced custom algorithm built into the Blood Oxygen app, which is designed to measure blood oxygen between 70 percent and 100 percent. On-demand measurements can be taken while the user is still, and periodic background measurements occur when they are inactive, including during sleep. All data will be visible in the Health app, and the user will be able to track trends over time to see how their blood oxygen level changes.



The new Blood Oxygen sensor and app conveniently measure the oxygen saturation of blood so users can better understand their overall fitness and wellness.

Apple is joining forces with researchers to conduct three health studies that include using Apple Watch to explore how blood oxygen levels can be used in future health applications. This year, Apple will collaborate with the University of California, Irvine, and Anthem to examine how longitudinal measurements of blood oxygen and other physiological signals can help manage and control asthma.

https://www.apple.com/newsroom/2020/09/apple-watch-series-6-delivers-breakthrough-wellness-and-fitness-capabilities/

CX-1287

3/9/22, 5:54 PM

Apple Watch Series 6 delivers breakthrough wellness and fitness capabilities - Apple

Separately, Apple will work closely with investigators at the Ted Rogers Centre for Heart Research and the Peter Munk Cardiac Centre at the University Health Network, one of the largest health research organizations in North America, to better understand how blood oxygen measurements and other Apple Watch metrics can help with management of heart failure. Finally, investigators with the Seattle Flu Study at the Brotman Baty Institute for Precision Medicine and faculty from the University of Washington School of Medicine will seek to learn how signals from apps on Apple Watch, such as Heart Rate and Blood Oxygen, could serve as early signs of respiratory conditions like influenza and COVID-19.



The Blood Oxygen sensor employs LEDs, along with photodiodes on the back crystal of Apple Watch Series 6.



#### **Design and Performance**

Apple Watch Series 6 improves performance through redesigned hardware that packs even more features and power into the same impressively small design. Using a new dual-core processor based on A13 Bionic in iPhone 11, the upgraded S6 SiP runs up to 20 percent faster, allowing apps to also launch 20 percent faster, while maintaining the same all-day 18-hour battery life. Additionally, Apple Watch Series 6 features the U1 chip and Ultra Wideband antennas, which will enable short-range wireless location to support new experiences, such as next-generation digital car keys. Apple Watch Series 6 offers faster charging, completing a full charge in under 1.5 hours, and improved battery life for tracking certain workouts, such as indoor and outdoor runs.

An enhanced Always-On Retina display on Apple Watch Series 6 is up to 2.5 times brighter than Apple Watch Series 5 outdoors when the user's wrist is

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down, making it much easier to see a watch face in bright sunlight. When their wrist is down, the user can also now access Notification Center and Control Center, tap on complications, and swipe to change faces without having to wake their watch screen.

#### **Always-On Altimeter**

The always-on altimeter provides real-time elevation all day long by using a new, more power-efficient barometric altimeter, along with GPS and nearby Wi-Fi networks. This feature allows for the detection of small elevation changes above ground level, up and down to the measurement of 1 foot, and can be shown as a new watch face complication or workout metric.

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#### **Apple Watch Collection**

This fall, customers have more choices than ever with stunning new cases and bands to suit every style preference. For the first time, a new blue color joins the silver, space gray, and gold aluminum case options, along with a (PRODUCT)RED Apple Watch with exclusive matching bright red bands. Stainless steel models are now available in graphite — a rich gray-black hue with a striking high-shine finish — and an updated classic yellow gold color. Apple Watch Edition is available in natural and space black titanium.

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Three all-new band styles offer customers innovative options that provide a tailored and comfortable fit without traditional clasps or buckles. In an industry first, the ultralight Solo Loop introduces a continuous and stretchable band design that comes in two materials: soft silicone and braided yarn. A special UV treatment process used on the soft silicone of the Solo Loop creates a smooth, silky finish, while a precision-braiding machine interweaves the 16,000 polyester yarn filaments, made of 100 percent recycled material, with ultrathin silicone threads, giving unique stretchability and a distinct look to the Braided Solo Loop. To ensure the best fit, a new sizing system offers nine available lengths for the Solo Loop styles. The first-of-its-kind Leather Link wraps elegantly around the wrist, effortlessly attaching on the other side with flexible molded magnets.

Apple Watch Nike now comes with new colors for the Nike Sport Band and Nike Sport Loop, and a new Nike Compact watch face allows for multiple Nike Run

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Club complications. Apple Watch Hermès offers stainless steel cases in silver or space black paired with Single or Double Tour styles in an assortment of vibrant new colors. The fall collection also unveils the Hermès Attelage Single Tour and slimmer Attelage Double Tour bands, which feature a refined connection to the case that reflects the brand's equestrian heritage, and a new Hermès Circulaire watch face that offers increased options for complications.

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With watchOS 7, customers can take personalization to the next level with seven new watch face options, including Stripes, Chronograph Pro, GMT, and Artist, while curating, discovering, and sharing new watch face configurations with others. New health and fitness features, including low-range VO2 Max, sleep tracking, automatic handwashing detection, and new workout types, can help users better understand overall well-being. Conveniently accessible on the wrist, Maps includes cycling directions and Siri offers language translation.

#### **Family Setup and Optimized Features for the Entire Family**

Family Setup<sup>4</sup> in watchOS 7 extends Apple Watch to the entire family by allowing kids and older family members of the household who do not have an iPhone to benefit from the connectivity, safety, and fitness features of Apple Watch. Kids can take advantage of communication and personalization capabilities, access Emergency SOS at any time, enjoy an Activity rings experience that has been optimized just for them, and utilize a new mode called Schooltime, which can help them stay focused and attentive while learning at home or in the classroom.

watchOS 7 also offers optimized features for older adults, starting with a simplified onboarding and configuration process, along with a refreshed X-Large face that shows the time and a rich complication at a glance. Older adults can

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also benefit from a new Health Checklist in the Health app on iPhone, which offers the ability to track whether health features like fall detection have been enabled in one centralized view.

#### **Pricing and Availability**

- Apple Watch Series 6 (GPS) starts at \$399 and Apple Watch Series 6 (GPS + Cellular) starts at \$499.
- Apple Watch Series 6 (GPS) is available to order today from apple.com and in the Apple Store app, with availability beginning Friday, September 18, in the US, Puerto Rico, and 27 other countries and regions.
- Apple Watch Series 6 (GPS + Cellular) is available to order today from apple.com and in the Apple Store app, with availability beginning Friday, September 18, in the US, Puerto Rico, and 21 other countries and regions. For carrier availability, visit apple.com/watch/cellular.
- Apple Watch Nike is available to order today from apple.com and in the Apple Store app, with availability beginning Friday, September 18, in the US, Puerto Rico, and more than 27 other countries and regions. For more information, visit apple.com/apple-watch-nike or nike.com/applewatch.
- Apple Watch Hermès is available to order today from apple.com and in the Apple Store app, with availability beginning Friday, September 18, in the US and more than 14 other countries and regions.
   For more information, visit apple.com/apple-watch-hermes or hermes.com/applewatchhermes.
- New Apple Watch bands are available to order today from apple.com and in the Apple Store app, with availability beginning Friday, September 18. Solo Loop and Braided Solo Loop in (PRODUCT)RED will be available in late October. Solo Loop and Braided Solo Loop are compatible with Apple Watch Series 4 and later.
- watchOS 7 will be available for Apple Watch Series 3 and later on September 16, and requires iPhone 6s or later running iOS 14. Not all features are available on all devices.
- When customers buy directly from Apple, Apple Watch Studio gives them the exclusive opportunity
  to pick their preferred case and band combination to create a look that is uniquely their own.
- Customers looking for convenient, contactless service are able to find many of the same shopping
  and support services from apple.com. Customers can chat with an Apple Specialist and get
  shopping help, choose monthly financing options, trade in eligible devices, and get Genius support
  and no-contact delivery. In-store pickup is also available. Customers are encouraged to check
  apple.com/retail for more information on the health and safety measures in place, and the services
  available at their local store.
- Customers in the US can trade in their eligible device for an Apple Gift Card or credit toward their purchase. If the device is not eligible for credit, Apple will recycle it for free.<sup>5</sup>
- Three months of Apple Fitness+ are included for customers who purchase Apple Watch Series 3 or later starting September 15, 2020. This extended trial is available for a limited time.<sup>6</sup>
- Customers in the US who buy directly from Apple can choose Apple Card Monthly installments to
  pay for their Apple Watch over 24 months, interest-free, and get 3 percent Daily Cash back all
  upfront. Customers who choose to pay in full with their Apple Card also get 3 percent Daily Cash
  back.
- Customers can extend their limited warranty with AppleCare+ and get accidental damage coverage and 24/7 priority access to technical support.
- Customers who buy Apple Watch directly from Apple can enjoy a free Online Personal Session with an Apple Specialist to help them explore and discover all the amazing things they can do with their new Apple Watch.<sup>7</sup>
- In line with Apple's commitment to the environment, there are industry-leading amounts of recycled content in Apple Watch Series 6, with 100 percent recycled rare earth elements in the Taptic Engine, nearly 100 percent recycled tungsten throughout the product, and a 100 percent recycled

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case on aluminum models. Apple is also helping the environment by removing the AC adapter that could become electronic waste from Apple Watch Series 6 packaging, and helping its Apple Watch manufacturing partners transition to renewable energy.

To see all of the latest announcements and photos from today's keynote event, check out the wrap-up on Apple Newsroom.

#### Share article



#### **Images of Apple Watch Series 6**

Download all images (4)

Apple revolutionized personal technology with the introduction of the Macintosh in 1984. Today, Apple leads the world in innovation with iPhone, iPad, Mac, Apple Watch, and Apple TV. Apple's five software platforms — iOS, iPadOS, macOS, watchOS, and tvOS — provide seamless experiences across all Apple devices and empower people with breakthrough services including the App Store, Apple Music, Apple Pay, and iCloud. Apple's more than 100,000 employees are dedicated to making the best products on earth, and to leaving the world better than we found it.

- 1. Blood Oxygen app measurements are not intended for medical use, including self-diagnosis or consultation with a doctor, and are only designed for general fitness and wellness purposes.
- 2. Battery life varies by use.
- 3. Not available in all countries.
- 4. Requires cellular models of Apple Watch Series 4 or later, or Apple Watch SE.
- 5. Trade-in values vary based on the condition, year, and configuration of your trade-in device, and may also vary between online and in-store trade-in. You must be at least 18 years old. Offer may not be available in all countries. In-store trade-in requires presentation of a valid government-issued photo ID (local law may require saving this information). Additional terms from Apple or Apple's trade-in partners may apply.
- 6. \$9.99 per month or \$79.99 per year after free trial. No commitment. Plan automatically renews until cancelled.
- 7. In most countries

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#### **Latest News**



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March 8, 2022



PRESS RELEASE

Apple unveils M1 Ultra, the world's most powerful chip for a personal computer

March 8, 2022



PRESS RELEASE

Apple introduces the most powerful and versatile iPad Air ever

March 8, 2022

The latest news and updates, direct from Apple.

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iPad	Apple Fitness+	Today at Apple	For Education Apple and Education Shop for K-12 Shop for College	Environment
iPhone	Apple News+	Apple Camp		Inclusion and Diversity
Watch	Apple Arcade	Apple Store App		Privacy
AirPods	iCloud	Refurbished and Clearance		Racial Equity and Justice
TV & Home	Apple One	Financing		Supplier Responsibility
iPod touch	Apple Card	Apple Trade In	For Healthcare Apple in Healthcare	About Apple
AirTag	Apple Books	Order Status		
Accessories	Apple Podcasts	Shopping Help	Health on Apple Watch	Newsroom
Gift Cards	App Store		Health Records on iPhone	Apple Leadership
			Troutin Noodrad on a richo	Career Opportunities
	Account		For Government	Investors
	Manage Your Apple ID		Shop for Government	Ethics & Compliance
	Apple Store Account		Shop for Veterans and Military	Events
	iCloud.com			Contact Apple

More ways to shop: Find an Apple Store or other retailer near you. Or call 1-800-MY-APPLE.

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United States

## EXHIBIT 11

Video file submitted concurrently herewith on a thumb drive

## **EXHIBIT 12**

From:

Adrian Perica [perica@apple.com]

Sent:

3/22/2013 1:04:44 PM

To: CC: Paul Jansen [PJansen@masimo.com] Steve Smith [srsmith@apple.com]

Subject:

Checking In

Paul,

Hope you had a good weekend. I wanted to loop back around on the NDA and next steps.

We reviewed your NDA internally but would prefer to use an Apple form for a couple of reasons. The largest is that our conversation will cover a range of topics across Apple (e.g., our MFI program, potential app development help, your technology roadmap, connecting to Apple retail, etc.). Second, there are some basic terms that we need in NDAs such as mutuality, residuals, termination date, need to disclose if required by law, etc. Yours is shorter, which I really liked, but we hacked it up so much that we concluded we ought to try using an Apple one.

I've copied Steve Smith on my team, who will run point on the NDA and scheduling next steps. He'll send you a standard Apple NDA later today.

As well, can we start working schedules for a meeting here in Cupertino? After some conversations internally, I'd like to cover the following topics in what's probably a a half day program, including breaks.

- **1. Overview of Masimo** 30 minutes Standard corporate intro stuff covering company, broad product line, market focus, internal org, key leaders that Apple might meet over time. Probably more "hospital/Healthcare" focused.
- **2. Overivew of iOS/Mobile Products -** 30 minutes Focus on those products you are doing in the "consumer" space. Probably your roadmap stuff here. Maybe how you see the industry evolving.
- **3. Overview of Technology** 1 hour Deeper dive into the actual optical technology and algorithms used in your tech. We at Apple have a tendency to want to dig deep. Purpose it to begin understanding how this "medical" tech could work in normal consumer settings (vs. controlled hospital settings). We're also interested to understand which measurements your technology can reliably take now and what's potentially on the roadmap. The idea is to see whether consumers can 'use' the measurements in their daily lives or whether they really are inputs to a medical doctor's periodic diagnosis or treatment of specific conditions.
- **4. Overview of Regulatory Process/Environment** 30 minutes Anything you can share for how you go thru the regulatory approval process, how Apple/smart phone folks are involved to date, and how you might like us to be involved going forward
- **5. Masimo requests of Apple right now** 30 minutes These are things you need from Apple right now for your product plans (e.g., Bluetooth connectivity, better intros into Retail, connections with Developer Relations, potential promotion in the App store, selling "joint solutions", etc.)
- **6. How Apple could integrate Masimo tech into Apple products -** 1 hour This is the more pie in the sky stuff. Let's discuss any ideas you have about how Apple could or should integrate some these technologies in our products. On our side, we want to specifically touch on things we're seeing in start-up land like the Basis watch, Valencell earbuds or LifeWatch smart phone. There's a ton more but these cover the water front from wearable electronics for fitness/wellness to "doctor in the box" ideas.



EXHIBIT 559

Cook

12/7/2022

Reported by: Michael P. Hensley, RDR
CA CSR #14114

MASA03217800

How does the above agenda look? It's broad, so we can move fast and plan on follow-up as necessary.

Steve will propose dates and attendees on our side, but it will be a combination of:

- Engineering
- Marketing
- Legal/Regulatory

Thanks, Adrian Case: 24-1285 Document: 25-3 Page: 106 Filed: 01/10/2024 CONFIDENTIAL BUSINESS INFORMATION REDACTED ENTIRELY FROM PAGES MAS-ADD-161 - MAS-ADD-162

## **EXHIBIT 13**Confidential Business Information

Case: 24-1285 Document: 25-3 Page: 107 Filed: 01/10/2024 CONFIDENTIAL BUSINESS INFORMATION REDACTED ENTIRELY FROM PAGES MAS-ADD-164 - MAS-ADD-165

### **EXHIBIT 14**

### Confidential Business Information

Case: 24-1285 Document: 25-3 Page: 108 Filed: 01/10/2024 CONFIDENTIAL BUSINESS INFORMATION REDACTED ENTIRELY FROM PAGES MAS-ADD-167 - MAS-ADD-172

# **EXHIBIT 15**Confidential Business Information

Case: 24-1285 Document: 25-3 Page: 109 Filed: 01/10/2024 CONFIDENTIAL BUSINESS INFORMATION REDACTED ENTIRELY FROM PAGES MAS-ADD-174 - MAS-ADD-178

# **EXHIBIT 16**Confidential Business Information

# **EXHIBIT 17**Confidential Business Information

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# UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON, D.C.

Before the Honorable Monica Bhattacharyya Administrative Law Judge

In the Matter of

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

COMPLAINANTS' CORRECTED INITIAL POST-HEARING BRIEF

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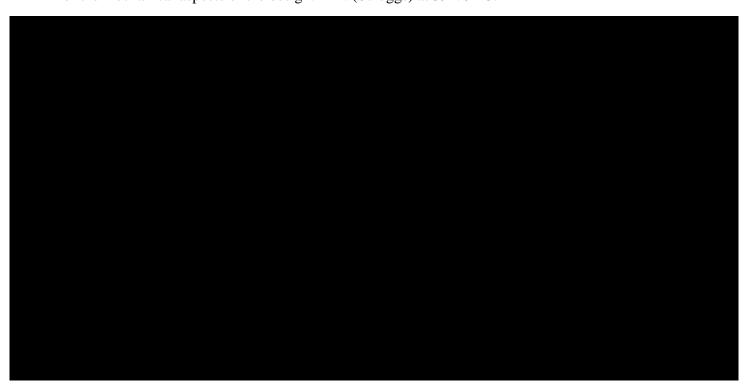
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estimation of the LED operating wavelengths. *Id.* at 10:32-39, Claim 7; Tr. (Goldberg) at 646:16-25. The invention allows the measurement of HbCO, "oxygen saturation[,] and pulse rate with increased accuracy or robustness." JX-0007 at 5:5-22.

#### **E.** The Products at Issue

#### 1. Masimo's Domestic Industry Products

Masimo developed all the domestic industry articles in the United States. Tr. (Kiani) at 119:9-12. The domestic industry articles for the '501, '502, '648, and '745 Patents are Masimo Watches shown in the demonstrative below from Stephen Scruggs, who was "responsible for all of the mechanical aspects of the design." Tr. (Scruggs) at 392: 9-13.



CDX-0005C.002 (citing CPX-0021aC; CPX-0029aC; CPX-0052aC; CPX-0058aC; CPX-0019aC; CPX-0020aC; CPX-0065aC; CPX-0155aC). Scruggs confirmed references to "Masimo W1 Watches" include both CPX-0146C and CPX-0155C. Tr. (Scruggs) at 431:14-16.

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a. Masimo Wat	ch
---------------	----

i. <u>Masimo and Cercacor's Wrist Pulse Oximetry Development</u>



CX-1482C at 4; Tr. (Kiani) at 116:8-9; CPX-0139C (photograph at CPX-0139aC).

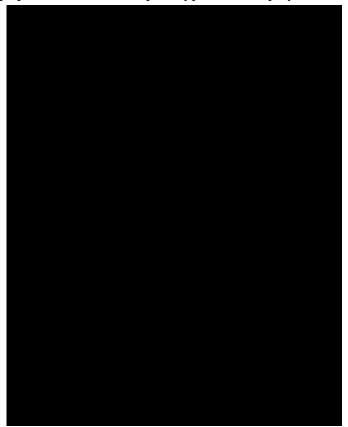
Tr. (Kiani) at 117: 8-9; CPX-0140C.

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CX-1483C. The photograph below shows the prototype Kiani displayed:



CPX-0140aC at 1; see also CX-1520C.

By Al-Ali

Tr. (Al-Ali) at 248:24-250:2, 328:8-16. He also filed a patent application in

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July 2015, a parent to the '745 Pater	at. <i>Id.</i> at 249:9-23. He resumed the project
Id. a	t 328:8-16; see also Tr. (Muhsin) at 342:17. Masimo and
Cercacor developed	Tr. (Muhsin) at 343: 3-4. The following
slide shows	Tr. (Kiani) at 122: 24-25.
CX-0364C at 19; see also CX-0691.	
In late 2019, Al-Ali's team	worked on Tr. (Al-Ali) at
256:23-259:5; CX-0352C; CX-0355	5C; CX-0356C. The Masimo measured pulse
oximetry parameters,	CX-0370C; Tr. (Al-Ali)
at 253:25-256:22.	
Tr. (Al-Ali) at 259:6-	260:10; CX-0357C.
Т	r. (Al-Ali) at 260:11-264:13, 270:1-22; CX-0375C; CPX-
0052C; CX-0378C.	
	Tr. (Al-Ali) at 272:16-275:12; CX-

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0378C at 32.
Tr. (Al-Ali) at 274:15-275:33. Arms is the industry method for measuring pulse oximetry
accuracy. Tr. (Al-Ali) at 274:15-24; CX-0273C (Amor) at 54:8-55:1.
Tr. (Al-Ali) at 265:15-269:25; CPX-0054C; CPX-0054aC; CPX-0056C;
CPX-0056aC.
ii. Masimo's Patent Practicing Articles
(a) <u>CPX-0021C</u>
The Masimo Watch, exemplified by CPX-0021C (photograph CPX-
0021aC),
(Scruggs) at 394:14-16, and Tr. (Scruggs) at 394:18.
Scruggs provided detailed descriptions of its features and
including SpO <sub>2</sub> . Tr. (Scruggs) at 402:24-403:7, 401:10-
11; 400:9-16, 403:21-404:2, 413:24-414:11. He also demonstrated this watch to both sides'
experts. Id. at 415:4-9; CX-0836C at 5; RX-0260C.
Apple claimed . But Scruggs
explained that,
Tr. (Scruggs) at 474:24-475:4.
Masimo
Id. at 475:8-15; Tr. (Al-Ali) at 250:15-255:18; see also id. at 255:19-256:22; CX-0370C
CPX-0022C; CPX-0022aC.

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Scruggs introduced numerous documents reflecting the design of CPX-0021C and
including CX-0656C, CPX-0014a, CPX-0014, CX-0679, CX-0836C,
CX-0600C, CX-1132C, and CX-0474C. Tr. (Scruggs) at 413:17-23, 414:4-15, 414:23-415:3,
415:16-23, 415:24-416:12.
(b) <u>CPX-0029C</u>
The Masimo Watch with the is exemplified by CPX-0029C and its
photograph CPX-0029aC. Tr. (Scruggs) at 395:7-24.
id. at 395:14-15. Scruggs described the
features of this watch <i>Id.</i> at 404:10-19, 404:12, 404:20-
21, 404:22-24, 405:1-7. He also demonstrated this watch to both sides' experts. RX-0263C.
Scruggs introduced numerous documents reflecting the design of CPX-0029C, including
CX-0658C, CX-0605C, CX-1137C, and CX-0704C. Tr. (Scruggs) at 416:13-17, 416:20-417:11.

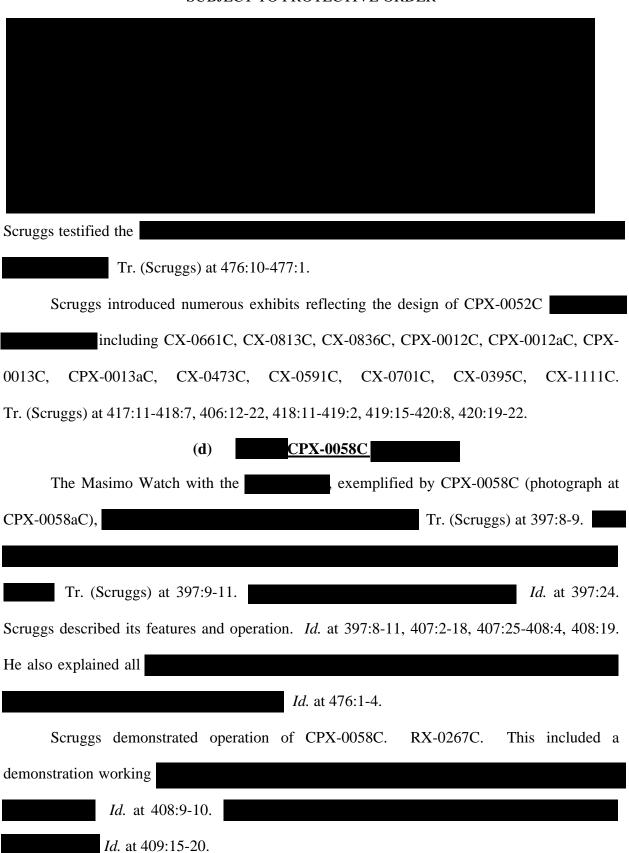
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Warren admitted the way to determine the accuracy of a device is to perform an Arms
calculation. Tr. (Warren) at 1277:12-20. He performed no such calculation. Id.
Tr. at 295:9-14.
(c) <u>CPX-0052C</u>
The Masimo Watch with the exemplified by CPX-0052C (photograph at
CPX-0052aC), was
Tr. (Scruggs) at 405:16-18. <i>Id.</i> at 396:10-11. Scruggs
described the features of this watch
Id. at 405:12-406:3, 406:6-11, 406:20-22. He also
demonstrated operation of CPX-0052C to both sides' experts,
Id. at 418:2-7; 419:3-11; CX-0836C at 4 (below).

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Scruggs introduced numerous exhibits reflecting the design of CPX-0058C
including CX-0665C, CX-0666C, CX-0815C, CPX-0141aC,
CX-0389C, CX-0536C, CX-0550C, CX-1124C, CX-0710C, and CX-0709C. Tr. (Scruggs) at
421:1-20, 422:6-423:22.
(e) CPX-0019C, CPX-0020C, CPX-0065C
The Masimo Watches with the exemplified by CPX-0019C, CPX-0020C,
and CPX-0065C,
Tr. (Scruggs) at 409:21-25; 410:1-4. These watches
Tr. (Scruggs) at 398:22-23. Scruggs
described the features and operation of these watches. Tr. (Scruggs) at 408:23-409:14, 421:14-
422:5. Scruggs demonstrated operation of a Masimo Watch
technical experts. RX-0268C.
Scruggs introduced numerous exhibits reflecting the design of CPX-0019C, CPX-0020C,
and CPX-0065C, including CX-0652C, CX-0653C, CX-0814C, CX-0654C, CX-0655C, CX-
1415C, CX-0675C, CX-0676C, CX-0812C, CX-0594C, CX-1129C, CX-0551C, CX-1125C,
CX-0390C, CX-0705C. Tr. (Scruggs) at 423:23-425:6, 425:15-23, 426:6-427:11.
Al-Ali confirmed CX-1634C are
Tr. (Al-Ali) at 313:14-314:7.
Tr. (Al-Ali) at 314:15-318:22; CX-
0494C.

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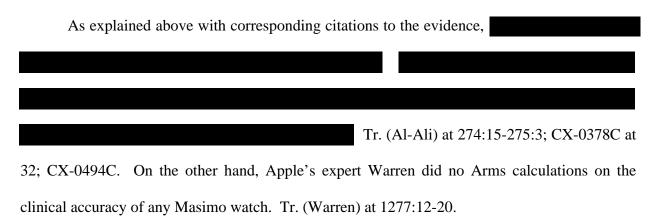
#### (f) Masimo W1

Masimo built the W1 Watch, as exemplified by CPX-0146C, CPX-0155C (photographs at CPX-0146aC and CPX-0155aC),

Tr. (Scruggs) at 399:1-3; Tr. (Scruggs) at 410:5-14; Tr. (Muhsin) at 350:11-22. Masimo COO Bilal Muhsin introduced an additional example of the W1 watch. Tr. (Muhsin) at 350:23-351:2, 351:17-352:4; CPX-0157C (CPX-0157aC); see also CPX-156aC. The W1 is Masimo's production version of the watch. Tr. (Scruggs) at 399:4-7.

Id. Scruggs described the features and operation of this watch. Id. at 410:9-24; 401:10-13; 410:25-411:2, 428:8-432:9.

Scruggs introduced numerous exhibits reflecting the design of the W1, including CPX-0146C, CX-0772C, CX-0784C, CX-0790C, CX-0685C, CX-1185C, CX-0806C, CX-0595C, CX-0392C, CX-0805C, CX-0801C, CX-0593C, CX-1128C. Tr. (Scruggs) at 428:8-432:9, 432:13-21.



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CDX-0011C.039 (citing CX-0063C at 1 (above); CX-1548C at 3 (showing chamfered edge on protrusion); CX-0070C at 1 (same)). Based on this evidence, Madisetti confirmed the Accused Products satisfy [30]. Tr. (Madisetti) at 699:4-19; *see also* CPX-0159; CX-0281C (Block) at 116:2-117:5 (Accused Products' "chamfered edge is a 45-degree machined—it's machined and edged away at 45 degrees"); CX-0063C at 2; CX-0070C at 3; CX-0062C at 1-2; CX-0069C at 1, 3.

Accordingly, the Accused Products infringe '648 Patent Claims 24 and 30. Tr. (Madisetti) at 699:20-25. Thus, the Accused Products infringe every Asserted Claim of the Multi-Detector Patents. *Id.* at 675:20-676:2; CDX-0011C.008.

#### D. <u>Domestic Industry – "Technical Prong"</u>

Masimo established the technical prong for all three Multi-Detector Patents by a preponderance of the evidence through testimony from Madisetti, Al-Ali and Scruggs, documentary evidence, and physical evidence of the Masimo Watches. *See Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003); *see also Certain Memory Modules*, Inv. No. 337-TA-1089, Comm'n Op., 2022 WL 834257, at \*43 (Feb. 1, 2022) (referring to "preponderance of the evidence" standard for technical prong).

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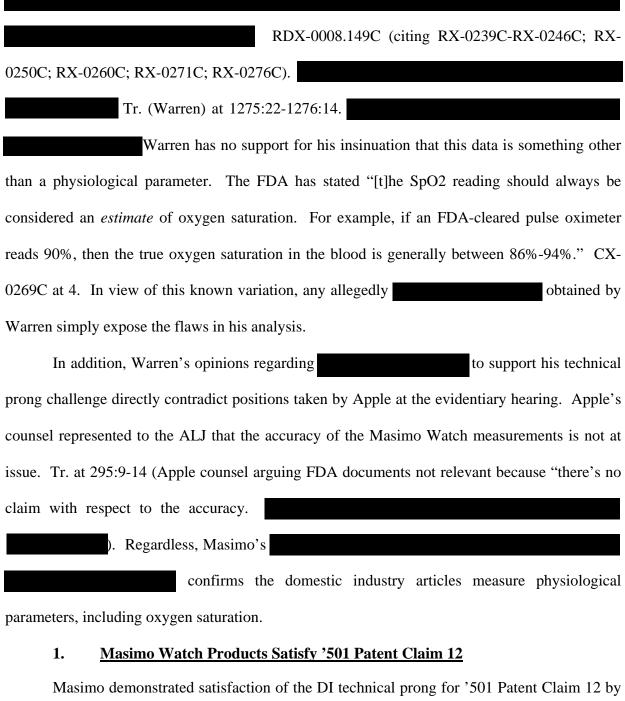
Apple's challenges to Masimo's domestic industry include two primary arguments presented by Warren. Both are insufficient. First, Warren opined he "was simply unable to visually confirm" several claim features. Tr. (Warren) at 1259:9-23. But the extensive testimony, documentary evidence, and physical evidence regarding those features render Warren's "visual analysis" irrelevant. Indeed, for several features Warren was "unable to visually confirm," such as the presence of multiple LEDs and photodiodes, Apple's other expert Sarrafzadeh never contested those features in analyzing these same watches for the '745 Patent. See Tr. (Sarrafzadeh) at 1122:3-10, 1127:14-18. The contemporaneous documents establish these items were present.

Second, Warren criticized the Masimo Watches as not being configured to non-invasively measure a physiological parameter because he was "not able to establish that they were producing physiological parameters" and he was "not provided with enough evidence to confirm that." Tr. (Warren) at 1258:9-25. But Masimo presented evidence, including testimony and evidence of demonstrations, establishing the Masimo Watches all non-invasively measure SpO<sub>2</sub>.

	Tr. (Al-Ali) at
272:16-275:12.	His insinuation that the display
of data from the Masimo Watches is something other than	n a physiological parameter is
conclusory and unsupported. Indeed, he admitted he never of	calculated "Arms," the industry
standard. Tr. (Warren) at 1277:12-20.	
Warren appears to rely primarily on what he refers to as	with the
Masimo W1.	
	DV 1470C at 0

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Masimo demonstrated satisfaction of the DI technical prong for '501 Patent Claim 12 by a preponderance of the evidence. *See Alloc*, 342 F.3d at 1375. As described below, the Masimo W1,

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#### a. Element [1PRE]

The W1, satisfy [1PRE]. Tr. (Madisetti) at 710:23-711:10; CDX-0011C.048 (for W1 citing CPX-0146C; CX-0685C; CX-0805C; CX-0392C; CX-0593C; CX-0595C; CX-0801C; CX-0806C; CX-0784C; CX-0790C; CX-1128C (CAD)); (for CPX-0019C; CPX-0020C; CPX-0065C; CX-0653C; CX-0655C; CX-0676C; CX-0390C; CX-0705C; CX-0709C; CX-1125C (CAD); CX-1068C (CPX-0019C video); CX-1069C (CPX-0020C video); CX-1072C (CPX-0065C video)); (for citing CPX-0058C; CX-0666C, CX-0536C; CX-1074C; CX-1124C (CAD)); (for citing CPX-0052C; CX-0661C; CX-0591C, CX-0836C at 4; CPX-0012C; CX-1111C (CAD)).

Scruggs testified all Masimo Watches "supported the ability to measure oxygen saturation and pulse rate" using processors

Tr. (Scruggs) at 393:17-20, 407:22-408:4 (describing functionality), 410:1-4 (confirming the same operation for and and ), 405:8-406:11 (describing functionality). Muhsin testified the Masimo Watches calculate oxygen saturation

Tr. (Muhsin) at 346:6-15.

The ability of the W1, to calculate oxygen saturation has been confirmed in numerous inspections of the devices, including those performed by Apple's experts and counsel. Tr. (Scruggs) at 399:15-400:2 (describing demonstration of W1 during deposition); RX-0268C (Apple's experts viewing CPX-0019C); RX-0269C (Apple's experts viewing CPX-0065C); RX-0270C (Apple's experts viewing CPX-0020C); RDX-0008.147C (demonstratives

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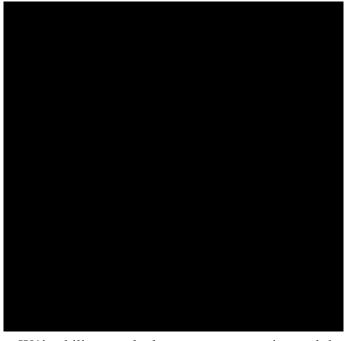
regarding observations by Apple's experts for "blood oxygen" and "pulse rate" citing RX-
0268C, RX, 0269C, RX-0270C); CX-1069C (Apple's counsel viewing CPX-0020C); CX-1068C
(Apple's counsel viewing CPX-0019C); CX-1072C (Apple's counsel viewing CPX-0065C);
RX-0266C ( inspection by Apple's experts); CX-1074C ( inspection by Apple's
counsel); RX-0265C (misspection by Apple's experts); CX-1062C inspection by
Apple's counsel); Tr. (Madisetti) at 715:20-716:12 (referencing demonstration by Scruggs to
Madisetti on March 1 and March 2, 2022). Moreover,
See, e.g., RX-
0239C; RX-0250C; RX-0271C; RX-0241C; RX-0242C; RX-0243C; RX-0244C; RX-0245C;
RX-0246C.
Al-Ali also testified that each of the Masimo Watches he introduced calculated oxygen
saturation, Tr. (Al-Ali) at 271:16-277:13, 315:16-
317:20.
Tr. (Al-Ali) at 271:16-277:13, 315:16-317:20; CX-0378C at 32; CX-
0494C.
Tr. (Al-Ali) at 318:15-22.
Tr. (Al-Ali) at 317:14-20.
Tr.
(Al-Ali) at 276:12-278:3; CX-0433C.
Tr. (Al-Ali) at
261:20-262:25, 263:6-13. Accordingly, the W1,
noninvasively measure a physiological parameter of a user.

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The W1, are also all "user-worn," as required by [1PRE]. The W1 and all contain a strap to place the watch on the user's wrist. CPX-0146C; CPX-0146aC; CPX-0155C; CPX-0155aC; CPX-0019C; CPX-0019aC; CPX-0020aC; CPX-0065C; CPX-0065aC; Tr. (Scruggs) at 408:20-409:14, 410:5-24.

An image of the Masimo W1 on a user's wrist and measuring oxygen saturation is shown below.



CX-0790C. The Masimo W1's ability to calculate oxygen saturation and the fact it is user-worn is also shown in its

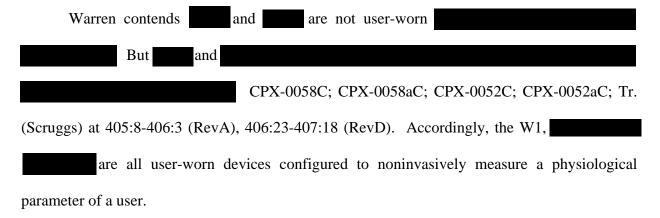


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CX-0685C at 1.



#### b. Element [1A]

The W1, satisfy [1A]. Tr. (Madisetti) at 711:14-712:4, 712:20-713:15. The locations of the LEDs in these Masimo Watches are shown below.

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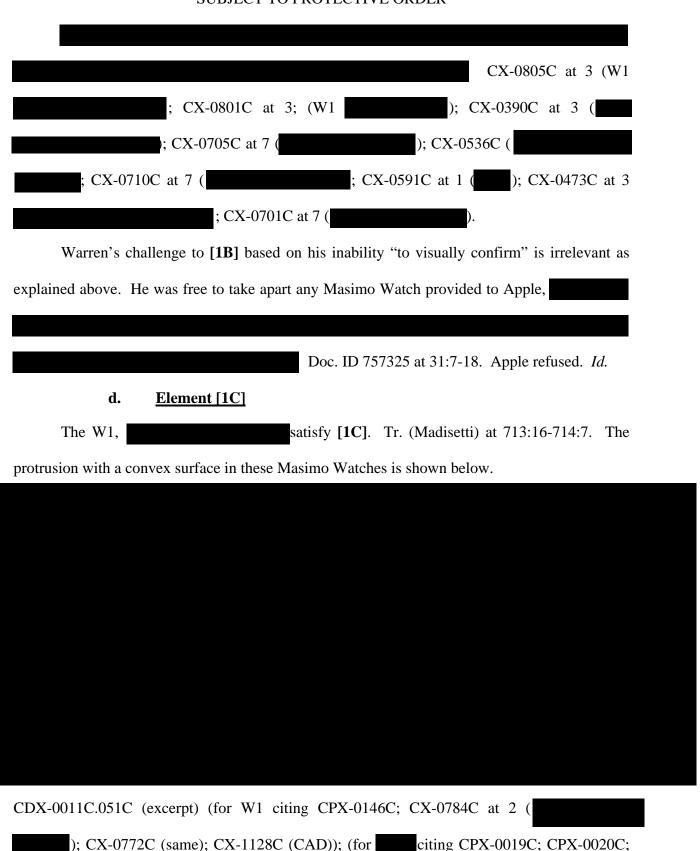
CDX-0011C.049 (excerpt) (for W1 citing CPX-0146C; CX-0784C at 2, 10; CX-0772C; CX-0805C at 3 (W1 s); CX-0801C at 4; CX-1128C (CAD) at 2, 4)); (for citing CPX-0019C; CPX-0020C; CPX-0065C; CX-0676C; CX-0390C at 1, 3 ( ); CX-1125C (CAD) at 2, 6, 7); (for citing CPX-0058C; CX-0666C; CX-0389C at 1, 3 ( ); CX-1124C (CAD) at 3-4, 8); (for citing CPX-0052C; CX-0661C; CX-0701C at 1, 6; CX-0473C at 1, 3; CX-0591C ( ); CX-1111C (CAD) at 3, 5, 6).

The below chart summarizes wavelengths of the various LEDs.

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502020	TO THO IDENTIFE ONDER
CX-0805C	at 3 (assembly W1); CX-0801C at 4 (schematic W1); CX-
0390C at 3 ); CX-0	0536C at 3 ( ); CX-0591C at 1 (
; CX-0473C	CX-0701C at 7 (
c. Element [1B]	
The W1,	satisfy [1B]. Tr. (Madisetti) at 712:5-19. The location
of the photodiodes in these Masimo W	Vatches are shown below.
CDX-0011C 050 (excernt) (for W1	citing CPX-0146C; CX-0784C at 2, 10; CX-0772C; CX-
CDA-0011C.030 (caccipi) (ioi W1	oning CIA-0170C, CA-0704C at 2, 10, CA-0772C, CA-
0805C at 3 (showing W1	); CX-1128C (CAD)); (for citing CPX-
0019C; CPX-0020C; CPX-0065C; C	CX-0653C (CPX-0019C photo); CX-0655C (CPX-0020C
photo); CX-0676C (CPX-0065C )	photo); CX-0390C at 3
); CX-1125C (CAD)); (f	for citing CPX-0058C; CX-0389C at 1, 3 (showing
	1124C (CAD)); (for citing CPX-0052C; CX-0661C
), CA-	11210 (ChD)), (101 Ling Cl A-0032C, CA-0001C
(photo); CX-0473C at 1, 3 (showing	); CX-1111C (CAD)).

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CPX-0065C; CX-1058C at 593 ( ); CX-1038C at 6 (same); CX-0676C
(same); CX-1125C (CAD)); (for citing CPX-0058C; CX-0815C (side view photo of CPX-
0058C ); CX-1124C (CAD)); (for citing CPX-0052C; CX-
0661C (CAD)).
CPX-0146C; CPX-0155C; CX-0784C at
1-6, 8-10, 12-13, CX-0772C; CX-1128C at 3; CPX-0019C; CPX-0020C; CPX-0065C; CX-
0814C; CX-1415C; CX-0812C; Tr. (Scruggs) at 424:5-8, 424:13-16, 424:22-24; CX-1125C at 8;
CPX-0058C; CX-0815C; CX-1124C; CPX-0052C; CX-0813C; CX-1111C at 2; CX-0395C.
e. Element [1D]
The W1, satisfy [1D]. Tr. (Madisetti) at 714:8-24. The openings
in these Masimo Watches are shown below. These openings extend through the protrusion and
allow light to reach the photodiodes after attenuation by the user's tissue.

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CPX-0065C; CX-1058C at 593 (photo showing openings); CX-1038C at 6 (same); CX-0676C (same); CX-1125C (CAD)) (for citing CPX-0058C; CX-1058C at 445 ( ); CX-1124C (CAD)) (for citing CPX-0052C; CX-0661C ( ); CX-1111C (CAD)).

CDX-0001C.048 (excerpt) (for W1 citing CPX-0146C; CX-0685C; CX-0805C; CX-0392C; CX-0593C; CX-0595C; CX-0801C; CX-0806C; CX-0784C; CX-0790C; CX-1128C (CAD)); (for citing CPX-0019C; CPX-0020C; CPX-0065C; CX-0653C; CX-0655C; CX-0676C; CX-0676C; CX-0655C; CX-0676C; CX-0655C; CX-0676C; CX-0655C; CX-0676C; CX-0655C; CX-0676C; CX-0655C; CX-0655C; CX-0676C; CX-0655C; CX-0

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0390C; CX-0705C; CX-0709C; CX-1125C (CAD); CX-1068C (CPX-0019C video); CX-1069C (CPX-0020C video); CX-1072C (CPX-0065C video)); (for citing CPX-0058C; CX-0666C; CX-0536C; CX-1074C; CX-1124C (CAD)); (for citing CPX-0052C; CX-0661C; CX-0591C; CX-0836C at 4; CPX-0012C; CX-1111C (CAD)). CX-1128C at 4 (W1) (left); CX-1125C at 6 ( right). CX-1124C at 4 (left); CX-1111C at 6 (right). Warren's challenge to [1D] based on his inability "to visually confirm" is irrelevant as explained above. Supra Section III.D.

for the reasons explained with respect to infringement. Supra Section III.C.2.a.ii.

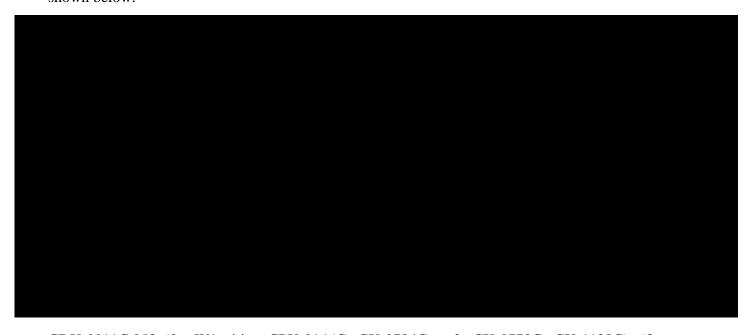
should be rejected

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#### f. Element [1E]

The W1, satisfy [1E]. Tr. (Madisetti) at 714:25-715:19. The opaque surfaces within the openings configured to avoid light piping in these Masimo Watches is shown below.



CDX-0011C.053 (for W1 citing CPX-0146C; CX-0784C at 2; CX-0772C; CX-1128C); (for citing CPX-0019C; CPX-0020C; CPX-0065C; CX-1038C at 6; CX-1125C); (for citing CPX-0058C; CX-0666C; CX-1124C); (for citing CPX-0052C; CX-0661C; CX-1111C).

Scruggs testified all Masimo Watches

Tr. (Scruggs) at 400:3-16; 401:18-22; 405:9-406:3, 406:23-407:18, 408:20-409:14, 410:5-24.

Tr. (Scruggs) at 400:3-16; 401:18-22; 405:9-

406:3, 406:23-407:18, 408:20-409:14, 410:5-24; see also Tr. (Al-Ali) at 261:17-262:6. CX-

in the W1. Tr. (Scruggs) at

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429:4-16.	
	Tr.
(Scruggs) at 400:17-24; see also Tr. (Al-Ali) at 261:17-262:6. Masimo conducts	
Tr. (Scruggs) at 392:19-23.	
As can be seen in the below images of these Masimo Watches,	

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CDX-0001C.048 (excerpt) (for W1 citing CPX-0146C; CX-0685C; CX-0805C; CX-0392C; CX-0593C; CX-0595C; CX-0801C; CX-0806C; CX-0784C; CX-0790C; CX-1128C (CAD)); (for citing CPX-0019C; CPX-0020C; CPX-0065C; CX-0653C; CX-0655C; CX-0676C; CX-0390C; CX-0705C; CX-0709C; CX-1125C (CAD); CX-1068C (CPX-0019C video); CX-1069C (CPX-0020C video); CX-1072C (CPX-0065C video)), (for citing CPX-0058C; CX-0666C; CX-0536C; CX-1074C; CX-1124C (CAD)); (for citing CPX-0052C; CX-0661C; CX-0591C; CX-0836C at 4; CPX-0012C; CX-1111C (CAD)).

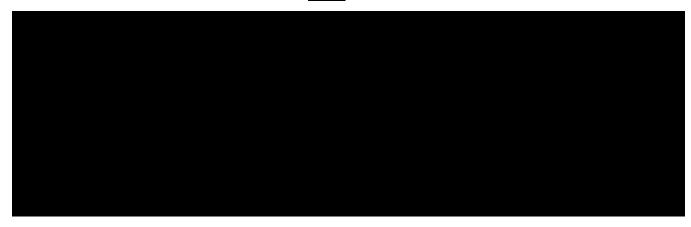
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The opaque lateral surfaces are also apparent in the representative CAD drawings corresponding to each of these Masimo Watches.



CX-1128C at 4 (W1) (left); CX-1125C at 6 ( right).



#### g. Element [1F]

The W1, satisfy [1F]. Tr. (Madisetti) at 715:20-716:21; CDX-0011C.054 (for W1 citing CPX-0146C; CX-0805C at 4 ); CX-0801C at 2-3 ( ); CX-0685C (W1 ); CX-0789C at 8 (W1 ); CX-0790C) (for citing CPX-0019C; CPX-0020C; CPX-0065C; CX-0705C at 2-3; CX-1062C at 30, 35) (for citing CPX-0058C; CX-0710C at 2-3; CX-1062C at 48 (

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); CX-1074C (same)) (for citing CPX-0052C; CX-0701C at 2; CPX-0012C;
CX-0836C at 4 (
All Masimo Watches
. Tr. (Scruggs) at 393:17-394:3.
The Masimo W1 included
Tr. (Scruggs) at 410:5-24.
CX-0801C at 4
CX-0801C at 3 (output
).
The . Tr. (Scruggs) at 408:20-409:14.
The
Tr. (Scruggs) at 407:22-408:4 (describing functionality), 410:1-4
(confirming the same operation for
CX-0705C at 7 (
; CX-0705C at 5 (
; CX-0705C at 4 (
); CX-0705C at 3 (
).
The included
Tr. (Scruggs) at 408:11-19.
Tr. (Scruggs) at 407:22-408:4. The

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schematic
CX-0710C at 7 (
); CX-0710C at 5 (
); CX-0710C at 4 (
); CX-0710C at 3
); Tr. (Scruggs) at
422:23-423:4.
The includes
Tr. (Scruggs) at 405:8-406:11. The Masimo Watches
. Tr. (Scruggs) at
393:17-394:3. The schematic
. CX-0701C at 6 (detectors
CX-0701C at 4 (
); CX-0701C at 3
); CX-0701C
at 2 (
Scruggs's testimony confirmed that . See '501
[1PRE], supra. Additionally, Scruggs demonstrated the functionality of the Masimo Watches to
Apple's counsel, Apple's experts and Madisetti. See '501 [1PRE], supra. Apple's experts also
obtained oxygen-saturation measurements using the Masimo W1. See '501 [1PRE], supra. Al-
Ali introduced
Tr. (Al-Ali) at 272:16-275:12.

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#### h. <u>Element [12]</u>

The satisfy [12]. Tr. (Madisetti) at 716:22-717:21. The convex surface of these Masimo Watches is shown below.



CDX-0011C.055 (for W1 citing CPX-0146C; CX-0784C at 1-6, 8-10, 12-13; CX-0772C; CX-1128C); (for citing CPX-0019C; CPX-0020C; CPX-0065C; CX-0812C; CX-0814C; CX-1415C; CX-1125C); (for citing CPX-0058C; CX-0815C; CX-1124C); (for citing CPX-0052C; CX-0813C; CX-1111C).

#### 2. Masimo Watch Products Satisfy '502 Patent Claim 28

Masimo demonstrated satisfaction of the DI technical prong for '502 Patent Claim 28 by a preponderance of the evidence. *See Alloc*, 342 F.3d at 1375. As described below, the Masimo W1, all practice Claim 28.

#### a. Element [28PRE]

The W1, satisfy [28PRE] for the reasons shown above for '501 [1PRE].

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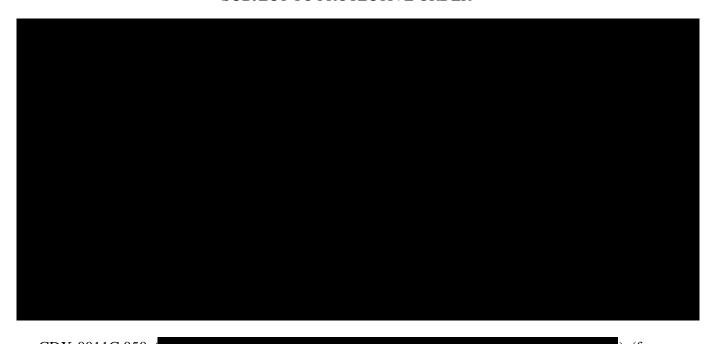
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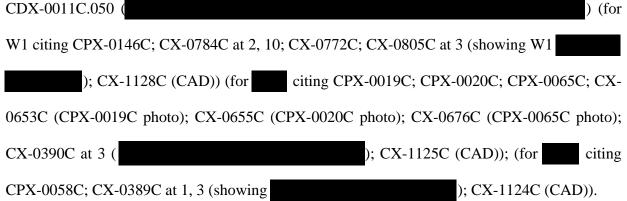
## **Element** [28A]

The W1,	satisfy [28A] for the reasons shown above for '501 [1A]. Tr.
(Madisetti) at 711:	14-712:4, 712:20-713:15. The W1 contains
	Tr. (Scruggs) at 410:5-24.
	·
	Tr. (Scruggs) at 408:20-409:14, 406:23-407:18.
Warren's c	hallenge to [28A] based on his inability "to visually confirm" is irrelevant as
explained above.	
c.	Element [28B]
The W1,	satisfy [28B] for the reasons shown above for '501 [1A] and
'502 <b>[28A]</b> . In the	ese Masimo Watches, the
meet [28B].	
d.	Element [28C]
The W1,	satisfy [28C] for the reasons shown above for '501 [1B].

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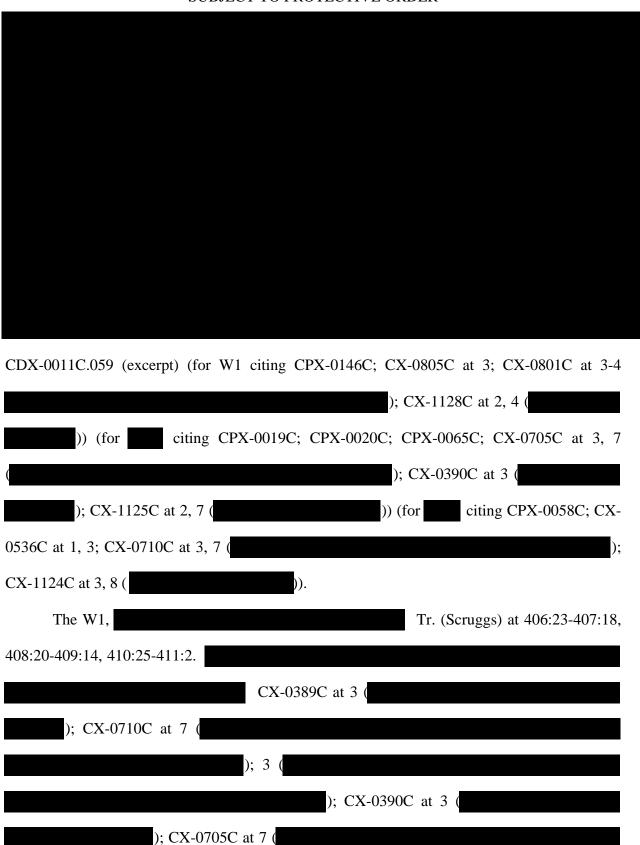




#### e. Element [28D]

The W1, satisfy [28D]. Tr. (Madisetti) at 720:21-721:5. The location of the thermistors on these Masimo Watches is shown below.

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), 3 (
); CX-0805C at 3 (W1
); CX-0801C at 4 (W1
), 3 (
).
allenge to [28D] based on his inability "to visually confirm" is irrelevant as
Element [28E]
satisfy [28E] for the reasons described above for '501 [1C].
Element [28F]
satisfy [28F] for the reasons described above for '501 [1D]
ne openings is defined by the opaque surface of the light barrier.
Element [28G]
satisfy [28G]. For each of the devices it is apparent there are
vs extending across each of the openings above the photodiodes. Apple does
te the Masimo Watches
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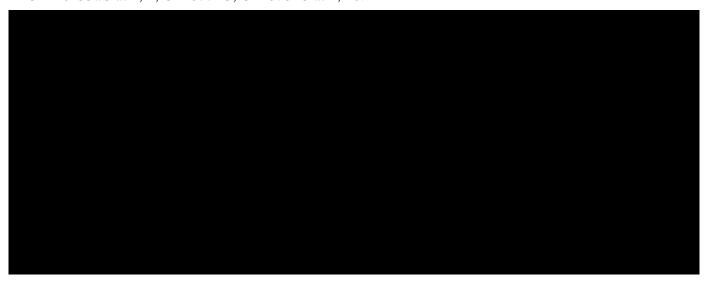
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W1

CPX-0155aC at 2, 4; CX-0772C; CX-0784C at 2, 10.



CPX-0019Ca at 2; CPX-0020Ca at 2; CPX-0065Ca at 2.



CPX-0058aC; CPX-0058C.

### i. Element [28H]

The W1, satisfy [28H]. Tr. (Madisetti) at 721:6-25. Scruggs testified all Masimo Watches

Tr. (Scruggs) at 400:3-

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	Id.
CDX-0011C.060 (fe	or W1 citing CPX-0146C; CX-0784C; CX-0772C; CX-1128C); (for
citing CPX-0019C;	CPX-0020C; CPX-0065C; CX-1038C at 6; CX-1125C); (for
CPX-0058C; CX-06	566C; CX-1124C).
j.	Element [28I]
The W1,	satisfy [28I] as shown above for '501 [1F] and '502 [28D].
<b>k.</b>	Element [28J]
The W1,	satisfy [28J] and Apple does not appear to dispute this
element. Tr. (Madi	setti) at 722:1-24; CDX-0011C.061 (for W1 citing CPX-0146C; CX-0685C
(W1	); CX-0790C; CX-0805C (
); CX-0801C	); CX-0806C (

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)) (for	citing CPX-0019C; CPX-0020C; CPX-
0065C; CPX-0141C; CX-0709C (	
); CX-0836C at 9, 12 (pho	otos of results
), 13; CX-1068C (CPX-0019C video);	CX-1069C (CPX-0020C video); CX-1072C
(CPX-0065C video); CX-1062C at 32 (CPX-0020C	C photo)) (for citing CPX-0058C; CX-
0709C (	); CX-1062C at
43 ); CX-1074C (video)).	
The W1 includes	
. Т	r. (Scruggs) at 410:5-24; 430:12-431:3.
CX-0392C at 3; Tr. (Scruggs) at 410:5-24; 430:12-	431:3. The W1
	CX-0685C at 1. It also
shows how one can	

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CX-0685C.
CA-0085C.
The include
Tr. (Scruggs) at
<u> </u>
408:20-409:14; 405:5-10, 406:23-407:18, 409:15-20; CPX-0141C. During the inspections by
Apple's experts and Madisetti, Scruggs demonstrated the ability of the
RX-0268C; RX-0269C; RX-0270C, CX-0836C at
101 02000, 101 02000, 101 02700, C11 00300 ut
9, 12, and 13 (screenshots from Madisetti demonstration).
CV 0700C at 2 /
CX-0709C at 3 ( ); Tr. (Scruggs) at 423:5-22;

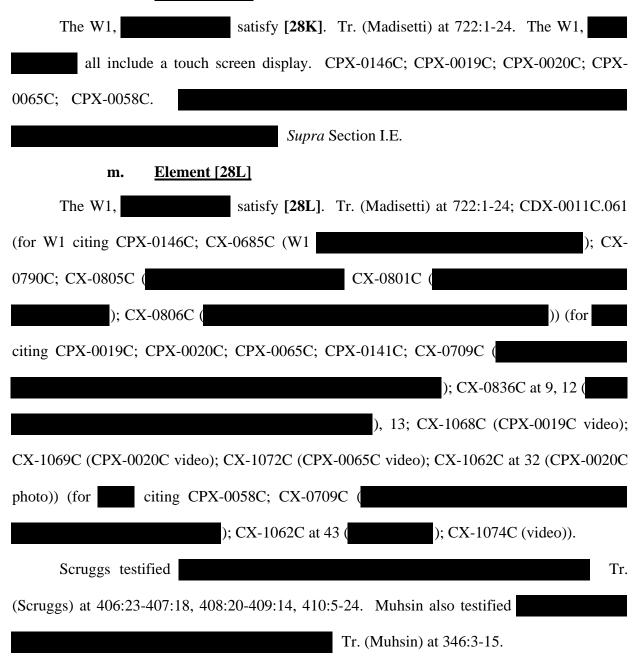
408:20-409:14; 410:1-4.

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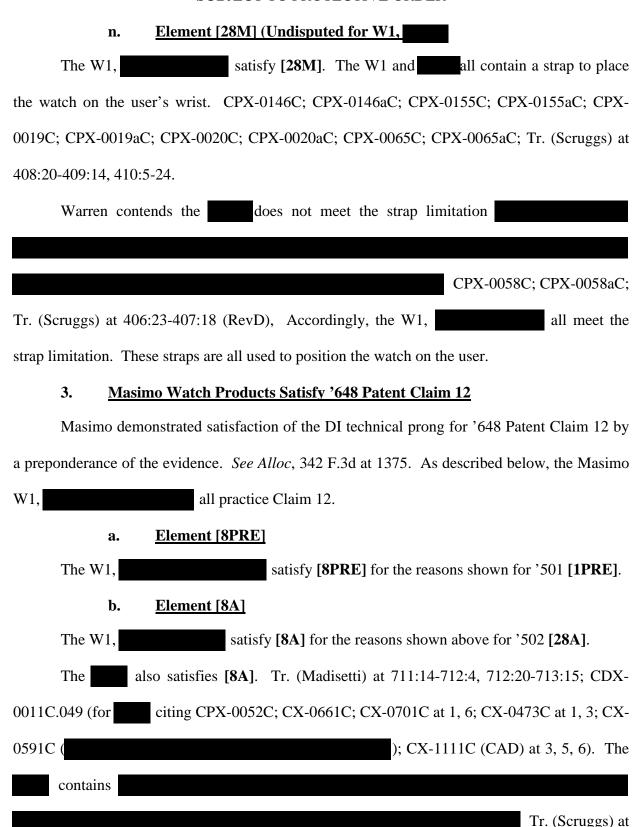
### l. Element [28K]



Warren's challenge to [28L] based on his inability "to visually confirm" is irrelevant as explained above.

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405:8-406:3.	
Warren's	challenge to [8A] based on his inability "to visually confirm" is irrelevant as
explained above.	•
c.	Element [8B]
The W1,	satisfy [8B] for the reasons shown above for '502 [28B].
als	so satisfies [8B] for the reasons shown above for '501 [1A] and '648 [8A].
	and accordingly meet [8B].
d	Element [8C]
The W1,	satisfy [8C] for the reasons shown above for '501 [1B].
e.	Element [8D]
The W1,	satisfy [8D] for the reasons shown above for '501 [1C]
and [1E].	
f.	Element [8E]
The W1,	satisfy [8E] for the reasons shown above for '501 [1D].
g.	Element [8F]
The W1,	satisfy [8F] for the reasons shown above for '502 [28G] and
Apple does not	appear to dispute this element.
The	also satisfies [8F]. From the it is apparent
	Apple does
not appear to dis	spute

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CPX-0052aC; CPX-0052C.

### h. Element [8G]

The W1, satisfy [8G] for the reasons shown above for '501 [1F].

### i. <u>Element [8H]</u>

The W1, satisfy [8H]. Tr. (Madisetti) at 725:19-726:1; CDX-0011C.066 (for W1 citing CPX-0146C; CX-0685C; CX-0805C; CX-0392C; CX-0593C; CX-0595C; CX-0801C; CX-0806C; CX-0784C; CX-0790C; CX-1128C (CAD)); (for citing CPX-0019C; CPX-0020C; CPX-0065C; CX-0653C; CX-0655C; CX-0676C; CX-0390C; CX-0705C; CX-0709C; CX-1125C (CAD); CX-1068C (CPX-0019C video); CX-1069C (CPX-0020C video); CX-1072C (CPX-0065C video)); (for citing CPX-0058C; CX-0666C; CX-0536C; CX-1074C; CX-1124C (CAD)); (for citing CPX-0052C; CX-0661C; CX-0591C; CX-0836C at 4; CPX-0012C; CX-1111C (CAD)).

Scruggs testified Tr. (Scruggs) at 405:8-406:3, 406:23-407:18, 408:20-409:14, 410:5-24.

CPX-0146C; CPX-0146aC; CPX-0155C; CPX-0155aC; CPX-0020C; CPX-0020aC; CPX-0019c; CPX-0019aC; CPX-0065C; CPX-0065aC; CPX-0058C; CPX-0058aC; CPX-0052aC.

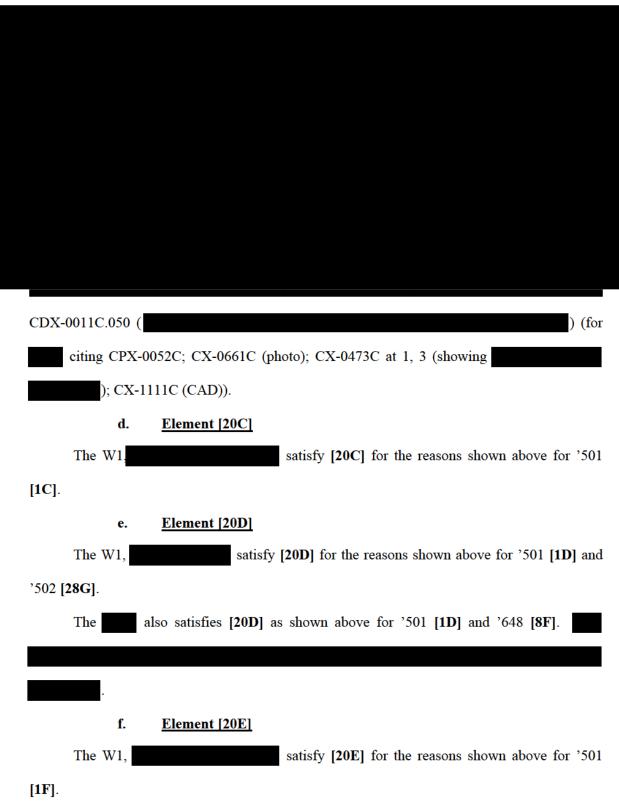
# CONFIDENTIAL INFORMATION REDACTED

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Sebuber 10 The IDent / Dent /
j. <u>Element [8I]</u>
The W1, satisfy [8I] for the reasons shown above for '502 [28M].
The also satisfies [81]. The
Tr. (Scruggs) at 405:8-406:3.
. CPX-0052C; CPX-0052aC.
k. Element [12]
The W1, satisfy [12] for the reasons described above for '501
[1PRE] and [1F].
4. Masimo Watch Products Satisfy '648 Patent Claims 24 and 30
Masimo demonstrated satisfaction of the DI technical prong for '648 Patent Claims 24
and 30 by a preponderance of the evidence. See Alloc, 342 F.3d at 1375. As described below,
the W1, all practice Claims 24 and 30.
a. Element [20PRE]
The W1, satisfy [20PRE] for the reasons shown for '501
[1PRE].
b. Element [20A]
The W1, satisfy [20A] for the reasons shown above for '501
[1A]. The at least three light emitting diodes (LEDs) recited in '501 [1A] are a plurality of light
emitting diodes (LEDs).
c. Element [20B]
The W1, satisfy [20B] for the reasons shown above for '502 [28C].
The also satisfies [20B].

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### g. <u>Element [24]</u>

The W1, satisfy [24] for the reasons shown above for '501 [1E].

The opaque material forming the light block is configured to substantially prevent light piping.

### h. <u>Element [30]</u>

The W1, satisfy [30]. Tr. (Madisetti) at 726:2-14. The chamfered edge on the protrusion of these Masimo Watches is apparent from the physicals and the CAD files corresponding to the physicals.



CDX-0011C.067 (for W1 citing CPX-0146C; CX-1128C (CAD)) (for citing CPX-0019C; CPX-0020C; CPX-0065C; CX-0814C (side profile photo); CX-1415C (same); CX-0812C (same); CX-1125C (CAD)) (for citing CPX-0058C; CX-1058C at 445 (side profile photo); CX-1124C (CAD)) (for citing CPX-0052C; CX-1111C (CAD)).

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CONTAINS CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

### E. Validity

To challenge the validity of the Multi-Detector Patents, Apple's counsel promised during opening that "the timeline tells the tale for this patent and for others as well." Tr. (Apple Opening) at 51:20-21. But Apple's "tale" contradicts the contemporaneous evidence, which demonstrated the inventive features of the Asserted Claims and Apple's own struggles with these same features.

Indeed, Apple's Series 0, 1, 2, 3, 4, and 5 watches did not measure oxygen saturation. Tr. (Mannheimer) at 1013:7-20. Contemporaneous documents show multiple senior Apple engineers recognized invention would be required to add pulse oximetry. They sought outside help, and even sought patent protection for what they viewed as innovative.

After and perceived invention by a team of engineers and scientists, the world's largest company finally released an oxygen saturation sensor in the Apple Watch Series 6. To do so, Apple used a convex, pressure-inducing protrusion with openings from the interior of the sensor to the skin surface, and a light blocking matrix separating the optical components, along with an to shape the light to obtain red/IR overlap. Apple even sought patent protection for this device in 2016. These are precisely the features Apple challenges here. Thus, contrary to Apple's counsel's bold proclamation regarding the Asserted Patents that "every single part of these claims was old as the hills," Tr. (Apple Opening) at 57:7-16, Apple engineers thought otherwise.

<sup>9</sup> Masimo discusses this timeline in detail below as providing objective evidence of nonobviousness.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

VIII. CONCLUSION

Masimo has satisfied the domestic industry requirement and shown that Apple infringes

the Asserted Patents. Apple failed to prove any of its defenses. The appropriate remedies for

Apple's violation of Section 337 are a limited exclusion order and a cease-and-desist order.

**CERTIFICATE OF WORD COUNT** 

The undersigned certifies that this brief complies with the word count requirements of

Order No. 49. Specifically, this brief contains no more than 69,250 words, including footnotes

and any image containing more than 20 words, but not including any image containing 20 or

fewer words, the caption, the tables of contents, authorities, acronyms and abbreviations, and

claim element identifiers, this word count certificate, the signature block, or the certificate of

service.

Dated: July 6, 2022

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# CONTAINS CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

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# **EXHIBIT 18**

### **PUBLIC VERSION**

# UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON, D.C.

Before the Honorable Monica Bhattacharyya Administrative Law Judge

In the Matter of CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

RESPONDENT APPLE INC.'S SECOND CORRECTED POST-HEARING BRIEF

#### **PUBLIC VERSION**

in creating a blood oxygen sensor for Apple Watch, including the complications of conducting measurements at the wrist; the need to fit the sensor inside a small device with many other components, without compromising the industrial design of Apple Watch; the difficulty of ensuring reliable measurements notwithstanding electromagnetic and vibrational interference from other components in the device; and the requirement for a device that works across a wide range of skin tones, body types, and consumer use patterns.

Through years of research and development, Apple's engineers overcame these obstacles and succeeded in creating the Blood Oxygen feature for Apple Watch—and did so without any use of Masimo confidential information or patented concepts. Contrary to the baseless allegations of copying levied by Complainants, Apple engineer after Apple engineer provided sworn testimony that they used no Masimo ideas, and instead built the Blood Oxygen feature based on their own ingenuity and hard work. Tr. [Venugopal] 833:11-17 ("Q. Dr. Venugopal, did you copy any other company's technology to make the blood oxygen feature for Apple Watch? A. No, I did not. Q. Did any of the colleagues you worked with in developing the blood oxygen feature for Apple Watch previously work at Masimo? A. No, they did not."); Tr. [Mehra] 893:9-17 ("Q. Have oy used any Masimo technology in any way in any of the work that you have done? A. No, I've not."); Tr. [Block] 914:1-7 ("Q. Dr. Block, did you take anything from Masimo in your work on Apple Watch? A. No. Q. Whose ideas are in the blood oxygen feature in Apple Watch? A. We developed that as a team independently. It's our ideas."); Tr. [Waydo] 933:5-11 ("Q. Did you or anyone on your team at Apple base any aspect of the design of Apple Watch on the design of a Masimo pulse oximeter? A. No."); id. at 950:1-15; Tr. [Land] 972:9-973:8 ("Q. To the best of your knowledge, sir, did any of the software or hardware developed by your team come from ideas that originated at Masimo? A. No."); Tr. [Mannheimer] 1007:22-1008:7 ("Q. From your position

### **PUBLIC VERSION**

at the heart of the research and development of the blood oxygen sensor for the Apple Watch, have you, Dr. Mannheimer, personally seen any evidence that any of the software or hardware came from Masimo ideas? A. No, I have not."). There is absolutely no evidence to the contrary.

The hearing evidence strongly suggested that *Masimo*, not Apple, was engaged in copying—both during development of the Masimo Watch, and in drafting patent claims.

Tr.

[Kiani] 167:10-16.

Tr. 1031:7-1032:4, 1033:10-1034:5; see also Tr. [Scruggs] 438:3-6

Yet Masimo's obvious effort to draft patent claims to cover Apple Watch—and then use those claims to secure an import ban on leading Apple Watch models, clearing a path for future sales of the Masimo Watch—has collapsed on the merits. The hearing evidence demonstrated the basic problems that Masimo faces. To draft claims to try to cover Apple Watch, Masimo was forced to use claim language directed to rudimentary technology common to both the clinical setting (from which the patents originated) and the consumer wearable setting (in which Apple Watch is sold). That rudimentary technology was disclosed in the prior art many times over, and in some instances many decades earlier.

### **PUBLIC VERSION**

Dated: September 2, 2022 Respectfully Submitted,

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# **EXHIBIT 19**

Trials@uspto.gov 571-272-7822

Entered: January 24, 2023

Paper 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC., Petitioner,

v.

MASIMO CORPORATION, Patent Owner.

IPR2022-01273 Patent 10,912,502 B2

Before JOSIAH C. COCKS, NEIL T. POWELL, and ROBERT A. POLLOCK *Administrative Patent Judges*.

COCKS, Administrative Patent Judge.

DECISION
Denying Institution of *Inter Partes* Review 35 U.S.C. § 314

IPR2022-01273 Patent 10,912,502 B2

### I. INTRODUCTION

Petitioner Apple Inc. filed a Petition (Paper 3, "Pet.") requesting *inter* partes review of claims 1–30 ("the challenged claims") of U.S. Patent No. 10,912,502 B1 (Ex. 1001, "the '502 patent"). Patent Owner Masimo Corporation filed a Preliminary Response (Paper 10, "Prelim. Resp."). We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition shows that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a); *see also* 37 C.F.R § 42.4(a) ("The Board institutes the trial on behalf of the Director.").

Having considered the arguments and evidence presented in the Petition, for the reasons described below, we do not institute *inter partes* review.

### A. Related Matters

The parties state that the '502 patent is the subject of *Masimo Corporation, et al. v. Apple Inc.*, ITC Inv No. 337-TA-1276. Pet. 1; Paper 5, 1. Patent Owner also identifies numerous additional patent applications, patents, and other *inter partes* review proceedings as related to the '502 patent. Paper 5, 1–3.

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<sup>&</sup>lt;sup>1</sup> Petitioner additionally filed a second Petition (IPR2022-01274) that also challenges claims 1–30 of the '502 patent.

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### B. The '502 Patent

The '502 patent is titled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User." Ex. 1001, code (54). The '502 patent summarizes its disclosure as follows:

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the noninvasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the noninvasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

Id. at 2:38–60.

The '502 patent describes that "[i]n noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger." *Id.* at 2:30–34.

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Figure 3C of the '502 patent is reproduced below:

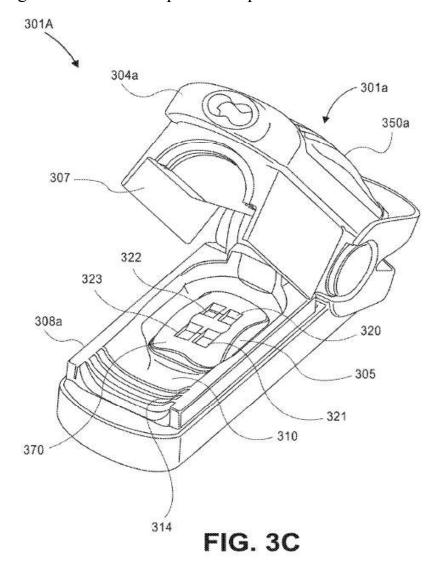


Figure 3C above illustrates an example sensor including a finger bed protrusion according to an embodiment of the disclosure. *Id.* at 5:52–55. Sensor 301a includes detector shell 306a (not numbered in Figure 3c) with lower area 308a that can "include absorbing opaque material . . . to reduce ambient light entering the sensor 301a." *Id.* at 19:4–12. Finger bed 310 includes convex protrusion 305 with openings or windows 320, 321, 322, and 322 that "mirror specific detector placement layouts such that light can impinge through the protrusion 305 onto" photodetectors (not illustrated in

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Figure 3C) that may be positioned beneath the protrusion. *Id.* at 19:42–48; 20:25–34.

# C. Challenged Claims

Petitioner challenges claims 1–30 of the '502 patent. Claims 1, 19, and 28 are independent claims. Claim 1 is representative and is reproduced below:

- 1. A user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising:
- a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;
- a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes arranged on an interior surface of the user-worn device and configured to receive light after attenuation by tissue of the user;

a protrusion comprising:

a convex surface extending over the interior surface, a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface, and

a plurality of windows, each of the windows extending across a different one of the openings; and one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate a measurement of the physiological parameter of the user.

Ex. 1001, 44:63-45:23.

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D. Alleged Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1-3, 5-9, 11-19, 25-	102	Mendelson-799, <sup>2</sup> Aizawa, <sup>3</sup>
27	103	Ohsaki, <sup>4</sup> Scharf, <sup>5</sup> and Dalke <sup>6</sup>
		Mendelson-799, Aizawa,
4, 10, 20–24, 28–30	103	Ohsaki, Scharf, Dalke, and
		Goldsmith <sup>7</sup>
1-3, 5-9, 11-19, 25-	103	Mendelson-799, Aizawa,
27	103	Kotanagi, <sup>8</sup> Scharf, and Dalke
	103	Mendelson-799, Aizawa,
4, 10, 20–24, 28–30		Kotanagi, Scharf, Dalke, and
		Goldsmith

Pet. 1. In addition to the references listed above, Petitioner relies on the Declaration of Dr. Thomas W. Kenny (Ex. 1003).

<sup>&</sup>lt;sup>2</sup> U.S. Patent No. US 6,801,799 B2 issued Oct. 5, 2004 ("Mendelson-799," Ex. 1006).

<sup>&</sup>lt;sup>3</sup> U.S. Patent Application Publication No. US 2002/0188210 A1 published Dec. 12, 2002 ("Aizawa," Ex. 1007).

<sup>&</sup>lt;sup>4</sup> U.S. Patent Application Publication No. US 2001/00562453 A1 published Dec. 27, 2001 ("Ohsaki," Ex. 1008).

<sup>&</sup>lt;sup>5</sup> U.S. Patent No. 6,330,468 B1 issued Dec. 11, 2001 ("Scharf," Ex. 1011).

<sup>&</sup>lt;sup>6</sup> U.S. Patent Application Publication No. US 2006/0211924 A1 published Sep. 21, 2006 ("Dalke," Ex. 1010).

<sup>&</sup>lt;sup>7</sup> U.S. Patent Application Publication US 2007/0093786 A1 published Apr. 26, 2007 ("Goldsmith," Ex. 1009).

<sup>&</sup>lt;sup>8</sup> PCT Application No. WO 2005/092182 A1 published Oct. 6, 2005 ("Kotanagi," Ex. 1015, 1016). All citations to Kotanagi in this Decision are to the English translation that is Exhibit 1016.

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### II. ANALYSIS

# A. Principles of Law

A petition must show how the construed claims are unpatentable under the statutory grounds it identifies. 37 C.F.R. § 42.104(b)(4). Petitioner bears the burden of demonstrating a reasonable likelihood that it would prevail with respect to at least one challenged claim for a petition to be granted. 35 U.S.C. § 314(a).

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, objective indicia of non-obviousness (i.e., secondary considerations). *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"In an [inter partes review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." Harmonic Inc. v. Avid Tech., Inc., 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring inter partes review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. See Dynamic Drinkware, LLC v. Nat'l Graphics,

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*Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

At this preliminary stage, we determine whether the information presented shows a reasonable likelihood that Petitioner would prevail in establishing that at least one of the challenged claims would have been obvious over the proposed prior art. We analyze the asserted grounds with the above-noted principles in mind.

### B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends the following in connection with a person of ordinary skill in the art:

A person of ordinary skill in the art relating to the subject matter of the '502 Patent as of July 3, 2008 ("POSITA") would have been a person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

Pet. 4 (citing Ex. 1003 ¶¶ 22–23).

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Patent Owner does not dispute this proposed level of skill. Prelim. Resp. 10.

For purposes of this Decision, we adopt Petitioner's proposal as reasonable and consistent with the prior art and the '502 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art may reflect an appropriate level of skill in the art).

### C. Claim Construction

We construe claims in the same manner used in a civil action under 35 U.S.C. § 282(b) "including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). When applying that standard, we interpret the claim language as it would have been understood by one of ordinary skill in the art in light of the specification. *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1279–80 (Fed. Cir. 2017). Thus, we give claim terms their ordinary and customary meaning as understood by an ordinarily skilled artisan. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

Neither party offers any express construction for any claim term. *See* Pet. 4; Prelim. Resp. 9. We determine that all claim terms should be given their ordinary and customary meaning and that it is unnecessary to make that meaning explicit for any term.

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# D. Grounds Based Primarily on Mendelson-799, Aizawa, Ohsaki, and Scharf

Petitioner contends that all of the challenged claims (i.e., claims 1–30) are rendered obvious based, at least in part, on the combined teachings of Mendelson-799, Aizawa, Ohsaki, and Scharf.<sup>9</sup> As expressed throughout its Preliminary Response, Patent Owner does not agree.

# 1. Overview of Mendelson-799

Mendelson-799 is a U.S. patent titled "Pulse Oximeter and Method of Operation," and discloses a sensor for non-invasive measurement of a blood parameter, which includes a sensor housing, a radiation source, and a detector. Ex. 1006, codes (54), (57).

Figure 7 of Mendelson-799 is reproduced below.

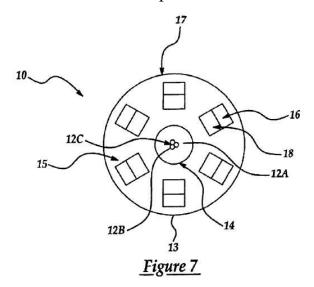


Figure 7 above illustrates optical sensor 10 with sensor housing 17 and light source 12, which includes three light emitting elements 12a, 12b, 12c. *Id.* at

<sup>&</sup>lt;sup>9</sup> The grounds also make reference to the teachings of Dalke and Goldsmith. We determine that resolution of this proceeding does not require detailed assessment of the teachings of any of those additional teachings.

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9:22–28. Optical sensor 10 includes an array of discrete detectors, i.e., "far" detectors 16 and "near" detectors 18, "arranged in two concentric ring-like arrangements . . . surrounding the light emitting elements." *Id.* at 9:29–34. Sensor housing 17 accommodates the light source, light shield, and detectors. *Id.* at 9:34–35.

# 2. Overview of Aizawa

Aizawa is a U.S. patent application publication titled "Pulse Wave Sensor and Pulse Rate Detector," and discloses a pulse wave sensor that detects light output from a light emitting diode and reflected from a patient's artery. Ex. 1007, codes (54), (57).

Figure 1(a) of Aizawa is reproduced below.

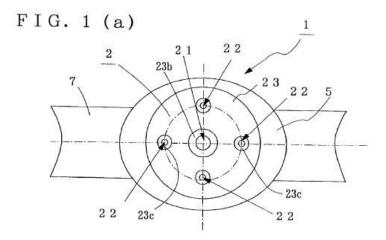


Figure 1(a) is a plan view of a pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(a), pulse wave sensor 2 includes light emitting diode ("LED") 21, four photodetectors 22 symmetrically disposed around LED 21, and holder 23 for storing LED 21 and photodetectors 22. *Id.* Aizawa discloses that, "to further improve detection efficiency, . . . the number of the photodetectors 22 may be increased." *Id.* ¶ 32, Fig. 4(a). "The same effect

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can be obtained when the number of photodetectors 22 is 1 and a plurality of light emitting diodes 21 are disposed around the photodetector 22." *Id.* ¶ 33.

Figure 1(b) of Aizawa is reproduced below.

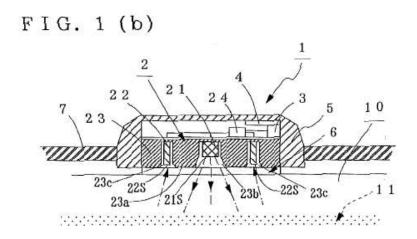


Figure 1(b) is a sectional view of the pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(b), pulse wave sensor 2 includes drive detection circuit 24 for detecting a pulse wave by amplifying the outputs of photodetectors 22. *Id.* ¶ 23. Arithmetic circuit 3 computes a pulse rate from the detected pulse wave and transmitter 4 transmits the pulse rate data to an "unshown display." *Id.* The pulse rate detector further includes outer casing 5 for storing pulse wave sensor 2, acrylic transparent plate 6 mounted to detection face 23a of holder 23, and attachment belt 7. *Id.* ¶ 23.

# 3. Overview of Ohsaki

Ohsaki is a U.S. patent application publication titled "Wristwatch-type Human Pulse Wave Sensor Attached on Back Side of User's Wrist," and discloses an optical sensor for detecting a pulse wave of a human body. Ex. 1008, code (54), ¶ 3.

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Figure 1 of Ohsaki is reproduced below.

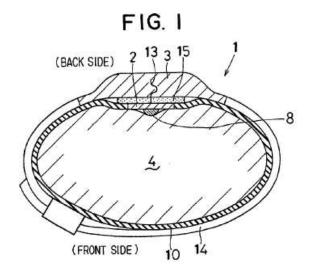
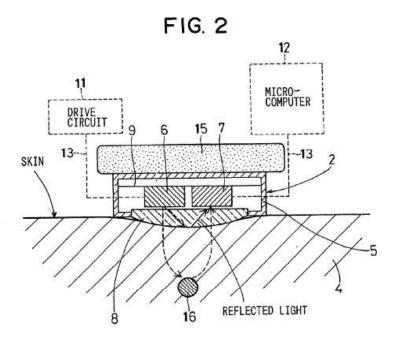


Figure 1 illustrates a cross-sectional view of pulse wave sensor 1 attached on the back side of user's wrist 4. *Id.* ¶¶ 12, 16. Pulse wave sensor 1 includes detecting element 2 and sensor body 3. *Id.* ¶ 16.

Figure 2 of Ohsaki, reproduced below, illustrates further detail of detecting element 2.



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Figure 2 illustrates a mechanism for detecting a pulse wave. *Id.* ¶ 13. Detecting element 2 includes, among other things, light emitting element 6, light receiving element 7, and translucent board 8. *Id.* ¶ 17.

# 4. Overview of Scharf

Scharf is titled "System Using Green Light to Determine Parameters of a Cardiovascular System." Ex. 1011, code (54). Scharf describes a reflectance oximeter that uses two green light source to detect oxygen saturation of hemoglobin in a volume of intravascular blood. *Id.* at 2:39–42.

Scharf's Figure 3 is reproduced below

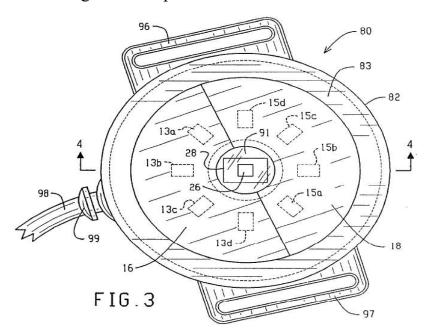


Figure 3 above shows a bottom plan view of an oximeter probe according to an embodiment. *Id.* at 3:40–41. The oximeter probe may include green lights formed of light emitting diodes (LEDs) 13, 15. *Id.* at 4:18–20. Scharf explains that, depending on the particular type of green light sources, green optical filters 16, 18 may be needed. *Id.* at 4:30–34.

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### 5. Discussion

A principal feature of each of the independent claims of the '502 patent lies in the structure and arrangement of a "protrusion" located over four photodiodes arranged on an interior surface of a user-worn device. In particular, in claim 1 that feature reads as follows:

a protrusion comprising:

- a convex surface extending over the interior surface,
- a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface, and
- a plurality of windows, each of the windows extending across a different one of the openings[.]

Ex. 1001, 45:11–19.

Thus, in claim 1, the protrusion feature requires a convex surface and multiple openings defined by an opaque surface and associated with a plurality of windows, with each window extending over a different opening. Independent claims 19 and 28 have similar requirements. Although not explicitly recited in claim 1, in the context of the '502 patent, the recited opaque surface is understood to aid in reducing "light piping" that reaches the photodiodes, which is an undesirable condition in which "light bypasses" the measurement site, e.g., human tissue, without being attenuated by that tissue. *See* Ex. 1001, 22:48–50; *see also* Prelim. Resp. 7–8 (description of light piping). <sup>10</sup>

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<sup>&</sup>lt;sup>10</sup> Independent claims 19 and 28, however, are explicit in reciting, respectively, that the opaque material is "configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue" (claim 19), and that that the "opaque surface [is] configured to reduce light piping" (claim 28).

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To arrive at the protrusion requirement in the claims, Petitioner presents a series of composite or modified figures that Petitioner contends would have emerged from the teachings of the prior art, specifically here, Mendelson-799, Aizawa, Ohsaki, and Scharf. At the outset, we reproduce again Mendelson-799's unmodified Figure 7:

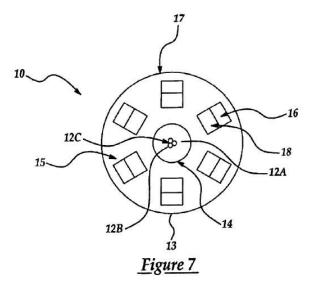
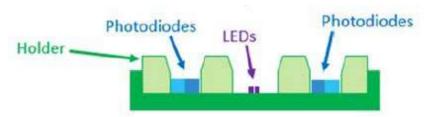


Figure 7 above illustrates Mendelson-799's optical sensor 10 with light sources 12a, 12b, and 12c and an "array of discrete detectors" (16 and 18) accommodated within sensor housing 17. *Id.* at 9:22–35. Although Mendelson-799 does not present a side view of the optical sensor illustrated in its Figure 7 (reproduced *supra*), Petitioner contends that Mendelson-799's Figure 7, when modified by the teachings of Aizawa to incorporate an opaque "holder," would appear as follows:



Pet. 22 (citing Ex.  $1003 \, \P \, 53$ ). In Petitioner's and Dr. Kenny's view, and as depicted in the modified figure above, the application of a holder from

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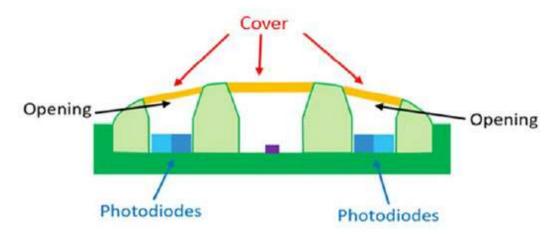
Aizawa onto Mendelson's optical sensor is asserted to result in multiple additional interior portions that extend in a manner so as to constitute a "protrusion" with multiple openings. *See, e.g., id.* at 23. The basis of Petitioner's proposed ground of unpatentability, however, does not end there. To account for the claim requirement pertaining to a convex surface, Petitioner proceeds to Ohsaki's teachings, and specifically its disclosure of translucent board 8 with convex surface, shown, for instance, in Ohsaki's Figure 2 (reproduce *supra*). Although, as Patent Owner notes, Ohsaki's board 8 is a singular structure that is translucent without openings (*see* Prelim. Resp. 37–38), Petitioner and Dr. Kenny are of the view that applying Ohsaki's teachings to Mendelson-799 and Aizawa, results in a further reconfiguration of the opaque holder said to arise from Mendeslon-799's and Aizawa's teachings as follows:



Id. at 28 (citing Ex. 1003  $\P$  61). Petitioner and Dr. Kenny generally contend that the above-reproduced figure on the right results from the combined teachings of Mendelson-799, Aizawa, and Ohsaki as a matter of simply being "use of a known technique to improve similar devices in the same way." *Id.* at 29–30 (citing Ex. 1003  $\P$  63).

Further still, in accounting for the requirements of the claims drawn to positioning different windows over each of the plurality of openings in the convex protrusion, Petitioner alleges that, in light of Scharf's teachings, the following further modified figure emerges:

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Pet. 31 (citing Ex. 1003 ¶¶ 65, 66). The reasoning for that further modified figure based on Scharf's teachings is premised on a desire to protect electronic components "from common environmental contaminants like dirt and moisture." *Id.* at 32.

Although it is certainly the case that an obviousness analysis may take into account the inferences and creative steps that a skilled artisan might glean from the teachings of the prior art (*see, e.g., KSR*, 550 U.S. at 418), one must be cognizant that "hindsight is not an available analytical mechanism to show obviousness." *See In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1381 (Fed. Cir. 2007) (Newman, J., dissenting). Indeed, "we cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention." *See Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017). Without the guidance provided by the claims of the '502 patent, it is difficult to conclude that Petitioner's postulation as to a particular structure that results from combining the teachings of Mendelson-799, Aizawa, Ohsaki, and Scharf is based on an objective assessment of what those teachings would have conveyed to a skilled artisan. It is clear from the Petition, however, that such structural configuration is necessary as the basis for

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Petitioner's approach to arriving at the structural requirements of the claims.<sup>11</sup>

At the outset, we share Patent Owner's view and that of its declarant, Dr. Duckworth (Ex. 2002), that none of the prior art on which Petitioner relies discloses a convex protrusion with multiple openings for multiple detectors. *See, e.g.*, Prelim. Resp 31; Ex. 2002 ¶ 76. The proposed amalgamation of prior art teachings includes, for instance, arranging a "holder" from Aizawa into a configuration that, for ill explained reasons, forms protruded portions of that holder containing multiple openings associated with photodetectors of Mendelson-799's optical sensor in an attempt to satisfy the structural requirements of the claim. *See, e.g.*, Pet. 21–22. In our view, however, Petitioner simply does not explain adequately why such configuration with respect to Mendelson-799's optical sensor results from the actual teachings of the prior art.

Furthermore, in an effort to next account for a convex shape of the protrusions and openings, Petitioner must rely on Ohsaki's convex translucent board under the premise that Ohsaki's board shape would "improve adhesion" or provide "improved user comfort" for a detector formed from a combination of Mendelson-799 and Aizawa. *See, e.g.*, Pet. 25–30. Yet, consistent with the arguments advanced by Patent Owner and Dr. Duckworth (*see, e.g.*, Prelim. Resp. 25–30; Ex. 2002 ¶¶ 109–111, 122–126), we are not satisfied that Petitioner adequately explains why a skilled

Although Petitioner, in a footnote, generally contends that "other examples" of composite figure configurations "could be conceived" so as to render the challenged claims obvious, Petitioner does not provide further assessment or explanation in that regard. *See* Pet. 23 n.5. We find that

general contention inadequately supported.

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artisan would have assessed that such reasoning applies with respect to a protrusion configured to have specific characteristics, e.g., multiple distinct openings and opaque surfaces, intended to provide a particular function, i.e., reduction of light piping, that is unaffiliated with concerns of adhesion.

Further still, we share Patent Owner's skepticism that the teachings of the prior art, and specifically Scharf, justifies Petitioner's theory that separate windows would be placed over different openings within a convex protrusion so as to provide a general benefit of protecting electronics from "contaminants like dirt and moisture." See, e.g., Pet. 32. Although Petitioner expresses that a "glass cover" generally may provide such protections, Petitioner does not explain adequately why, even if true, that the teachings on which Petitioner relies give rise to the particular window configuration required by the claims. See id. We also find credible Dr. Duckworth's testimony that Scharf's teachings applied to a combination of Mendelson, Aizawa, and Ohsaki do not convey reasonably to a skilled artisan the positioning of windows over the openings of a convex protrusion in the manner urged by Petitioner. See, e.g., Ex. 2002 ¶¶ 90–93. Moreover, left wanting from Petitioner's theories is why a person of ordinary skill in the art would seek to apply Scharf's teachings as to a sensor face incorporating particular green optical filters 16, 18 intended to affect the output of light *emitters* (e.g., LEDs), so as to produce the particular placement of windows within different openings associated with the light detectors (i.e., photodiodes) of any combination of Mendeslon-799, Aizawa, and Ohsaki.

On the record before us here, we find questionable Petitioner's and Dr. Kenny's assessment and reasoning as to what a skilled artisan would have understood from the combined teachings of Mendelson-799, Aizawa,

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Ohsaki, and Scharf as proposed by Petitioner here. We find persuasive Patent Owner's arguments that Petitioner's and Dr. Kenny's assessments are grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art. *See, e.g.*, Prelim. Resp. 26–30. Dr. Duckworth's testimony that one of ordinary skill in the art would not have combined the teachings of the prior art in the manner advocated by Petitioner supports Patent Owner's arguments. *See, e.g.*, Ex. 2002 ¶¶ 90–93, 109–111, 122–126.

Based on the record here, we conclude that Petitioner has not shown a reasonable likelihood of success based on any of the proposed grounds that involve the combined teachings of Mendelson-799, Aizawa, Ohsaki, and Scharf.<sup>12</sup>

## E. Ground Based on Mendelson-799, Aizawa, Kotanagi, and Scharf

Petitioner also contends that all of the challenged claims are rendered obvious based largely on the combined teachings of Mendelson-799, Aizawa, and Kotanagi. Patent Owner does not agree.

## 1. Overview of Kotanagi

Kotanagi is titled "Biological Information Measuring Device." Ex. 1016, code (54). Kotanagi describes that a biological information measuring device can include a biological sensor including a body and a protrusion formed on the lower surface of the body. *Id.* at code (57).

<sup>12</sup> The additional teachings of Goldsmith and Dalke are not offered by Petitioner to overcome the deficiencies discussed with respect to the combination of Mendelson-799, Aizawa, Ohsaki, and Scharf.

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Kotanagi explains that the protrusion can be formed with a "curved surface." *Id.* at  $\P 80$ .

## 2. Discussion

Petitioner proposes that all of the challenged claims are unpatentable based, at least in part, on the combined teachings of Mendelson-799, Aizawa, Kotanagi, and Scharf. Kotanagi's teachings are advanced by Petitioner as being analogous to, or alternative of, those of Ohsaki. *See, e.g.*, Pet. 90–94. In particular, Petitioner specifies that it applies Kotanagi's teachings for "the same reasons" as was proposed for the grounds including Ohsaki and that Kotanagi provides "additional/alternative motivation" to apply a convex protrusion in conjunction with the combined teachings of Mendelson-799 and Aizawa. *See, e.g.*, *id.* at 94.

In our view, Petitioner's proposed grounds of unpatentability for the challenged claims fare no better based on Kotanagi's teachings than they did for those grounds based on Ohsaki's teachings. For the same reasons discussed above, we conclude that Petitioner has not shown a reasonable likelihood of success in connection with any of its proposed grounds that involve the combined teachings of Mendelson-799, Aizawa, Kotanagi, and Scharf.<sup>13</sup>

## III. CONCLUSION

Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.

<sup>13</sup> Here, too, the additional teachings of Goldsmith and Dalke are not offered to overcome the deficiencies identified with respect to the combination of Mendelson-799, Aizawa, and Kotanagi.

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## IV. ORDER

In consideration of the foregoing, it is

ORDERED that Petitioner's request for an *inter partes* review of claims 1–30 of the '502 patent is *denied* and no trial is instituted.

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# **EXHIBIT 20**

Trials@uspto.gov 571-272-7822

Paper 15 Entered: January 24, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC., Petitioner,

v.

MASIMO CORPORATION, Patent Owner.

IPR2022-01274 Patent 10,912,502 B2

Before JOSIAH C. COCKS, NEIL T. POWELL, and ROBERT A. POLLOCK *Administrative Patent Judges*.

COCKS, Administrative Patent Judge.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

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## I. INTRODUCTION

Petitioner Apple Inc. filed a Petition (Paper 3, "Pet.") requesting *inter* partes review of claims 1–30 ("the challenged claims") of U.S. Patent No. 10,912,502 B1 (Ex. 1001, "the '502 patent"). Patent Owner Masimo Corporation filed a Preliminary Response (Paper 10, "Prelim. Resp."). We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition shows that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a); see also 37 C.F.R § 42.4(a) ("The Board institutes the trial on behalf of the Director.").

Having considered the arguments and evidence presented in the Petition, for the reasons described below, we do not institute *inter partes* review.

#### A. Related Matters

The parties state that the '502 patent is the subject of *Masimo Corporation, et al. v. Apple Inc.*, ITC Inv No. 337-TA-1276. Pet. 1; Paper 5, 1. Patent Owner also identifies numerous additional patent applications, patents, and *inter partes* review proceedings as related to the '502 patent. Paper 5, 1–3.

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<sup>&</sup>lt;sup>1</sup> Petitioner additionally filed another Petition (IPR2022-01273) that also challenges claims 1–30 of the '502 patent.

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## B. The '502 Patent

The '502 patent is titled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User." Ex. 1001, code (54). The '502 patent summarizes its disclosure as follows:

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the noninvasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the noninvasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

Id. at 2:38–60.

The '502 patent describes that "[i]n noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger." *Id.* at 2:30–34.

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Figure 3C of the '502 patent is reproduced below:

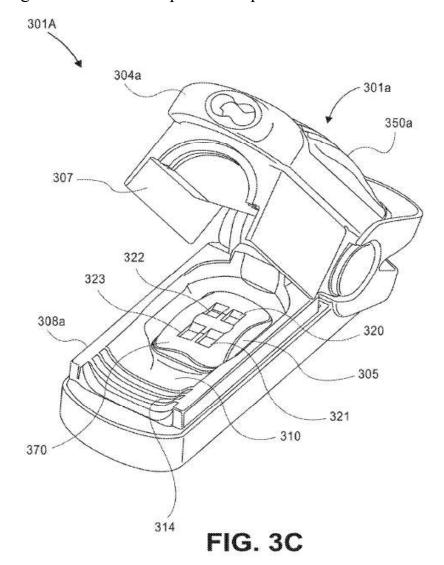


Figure 3C above illustrates an example sensor including a finger bed protrusion according to an embodiment of the disclosure. *Id.* at 5:52–55. Sensor 301a includes detector shell 306a (not numbered in Figure 3c) with lower area 308a that can "include absorbing opaque material . . . to reduce ambient light entering the sensor 301a." *Id.* at 19:4–12. Finger bed 310 includes convex protrusion 305 with openings or windows 320, 321, 322, and 322 that "mirror specific detector placement layouts such that light can impinge through the protrusion 305 onto" photodetectors (not illustrated in

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Figure 3C) that may be positioned beneath the protrusion. *Id.* at 19:42–48; 20:25–34.

## C. Challenged Claims

Petitioner challenges claims 1–30 of the '502 patent. Claims 1, 19, and 28 are independent claims. Claim 1 is representative and is reproduced below:

- 1. A user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising:
- a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;
- a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes arranged on an interior surface of the user-worn device and configured to receive light after attenuation by tissue of the user;

a protrusion comprising:

a convex surface extending over the interior surface, a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface, and

a plurality of windows, each of the windows extending across a different one of the openings; and one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate a measurement of the physiological parameter of the user.

Ex. 1001, 44:63-45:23.

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## D. Alleged Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1-3, 5-7, 9, 11-18	103	Lumidigm, <sup>2</sup> Scharf, <sup>3</sup> Kotanagi <sup>4</sup>
4, 8, 10, 19–27, 28–30	103	Lumidigm, Scharf, Kotanagi, Tran <sup>5</sup>

Pet. 1. In addition to the references listed above, Petitioner relies on the Declaration of Dr. Thomas W. Kenny (Ex. 1003).

## II. ANALYSIS

## A. Principles of Law

A petition must show how the construed claims are unpatentable under the statutory grounds it identifies. 37 C.F.R. § 42.104(b)(4). Petitioner bears the burden of demonstrating a reasonable likelihood that it would prevail with respect to at least one challenged claim for a petition to be granted. 35 U.S.C. § 314(a).

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

<sup>&</sup>lt;sup>2</sup> U.S. Patent No. 7,620,212 B1 issued Nov. 17, 2009 ("Lumidigm," Ex. 1006). Although Jeffrey G. Allen is listed as the first named inventor of the U.S. Patent No. 7,620,212 B2, Lumidigm, Inc. is listed as the Assignee. *See* Ex. 1006, code (73). Like the parties in their briefings in this proceeding, we refer to the noted patent as "Lumidigm."

<sup>&</sup>lt;sup>3</sup> U.S. Patent No. 6,330,468 B1 issued Dec. 11, 2001 ("Scharf," Ex. 1025).

<sup>&</sup>lt;sup>4</sup> PCT Application No. WO 2005/092182 A1 published Oct. 6, 2005 ("Kotanagi," Ex. 1007 (English translation)).

<sup>&</sup>lt;sup>5</sup> U.S. Patent No. 9,820,658 B2 issued Nov. 21, 2017 ("Tran," Ex. 1008).

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KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, objective indicia of non-obviousness (i.e., secondary considerations). Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966).

"In an [inter partes review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." Harmonic Inc. v. Avid Tech., Inc., 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring inter partes review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in inter partes review).

At this preliminary stage, we determine whether the information presented shows a reasonable likelihood that Petitioner would prevail in establishing that at least one of the challenged claims would have been obvious over the proposed prior art. We analyze the asserted grounds with the above-noted principles in mind.

## B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom* 

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Accessories, Inc. v. Jeffrey-Allan Indus. Inc., 807 F.2d 955, 962 (Fed. Cir. 1986); Orthopedic Equip. Co. v. U.S., 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends the following in connection with a person of ordinary skill in the art:

A person of ordinary skill in the art relating to the subject matter of the '502 Patent as of July 3, 2008 ("POSITA") would have been a person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

Pet. 2 (citing Ex. 1003 ¶¶ 40–41).

Patent Owner does not dispute this proposed level of skill. Prelim. Resp. 10.

For purposes of this Decision, we adopt Petitioner's proposal as reasonable and consistent with the prior art and the '502 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art may reflect an appropriate level of skill in the art).

## C. Claim Construction

We construe claims in the same manner used in a civil action under 35 U.S.C. § 282(b) "including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). When applying that standard, we interpret the claim

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language as it would have been understood by one of ordinary skill in the art in light of the specification. *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1279–80 (Fed. Cir. 2017). Thus, we give claim terms their ordinary and customary meaning as understood by an ordinarily skilled artisan. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

Neither party offers any express construction for any claim term. *See* Pet. 4; Prelim. Resp. 9. We determine that all claim terms should be given their ordinary and customary meaning and that it is unnecessary to make that meaning explicit for any term.

## D. Grounds Based on Lumidigm, Scharf, and Kotanagi

Petitioner contends that all of the challenged claims (i.e., claims 1–30) are rendered obvious based, in part, on the combined teachings of Lumidigm, Scharf, and Kotanagi.<sup>6</sup> As expressed throughout its Preliminary Response, Patent Owner does not agree.

# 1. Overview of Lumidigm

Lumidigm is titled "Electro-Optical Sensor." Ex. 1006, code (54). Lumidigm's Abstract is reproduced below:

Methods and systems are provided that extend the functionality of electro-optical sensors. A device has a multiple light sources, a light detector, and a processor configured to

<sup>&</sup>lt;sup>6</sup> For claims 3, 4, 6, 9, 10, 20, 21, 23, 24, 26–30, Petitioner additionally relies on Tran.

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operate the light sources and the light detector to perform distinct functions. At least one of the distinct functions includes a biometric identification function in which light is propagated from the plurality of light sources through presented material. The propagated light is received with the light detector, with the presented material being identified from the received light. Another of the distinct functions includes a nonidentification function performed with the light sources and the light detector.

*Id.* at code (57).

Lumidigm's Figure 2 is reproduced below:

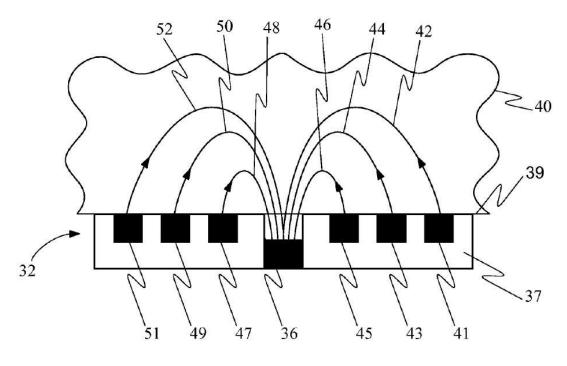
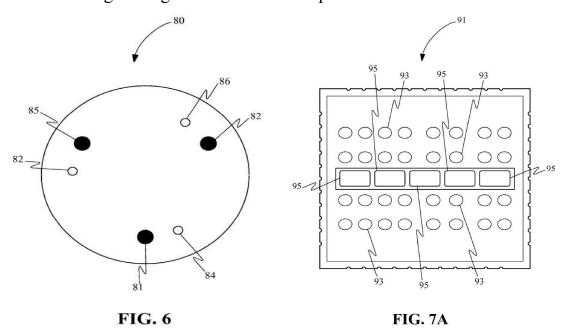


FIG. 2

Figure 2 above depicts a "cross-sectional view of a biometric sensor element couple to a tissue surface showing multiple mean optical paths." *Id.* at 4:45–47. Sensor head 32 includes light sources 41, 43, 45, 47, 49, 51 and detector 36. *Id.* at 7: 5–10. Optical paths 42, 44, 46, 48, 50, 52 show light passing through tissue 40. *Id.* Sensor head 32 is formed of optically opaque material 37.

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Lumidigm's Figures 6 and 7A are reproduced below:



Figures 6 and 7A above illustrate top-views of biometric sensors according to two embodiments of the invention. *Id.* at 4:60–67. In Figure 6, light sensor 80 includes light sources 82, 84, 86 positioned relative to detectors 81, 83, 85. *Id.* at 9:14–16.<sup>7</sup> In Figure 7A, sensor 91 includes two rows of light sources 93 and one robe of detectors 95. *Id.* at 9:27–30.

# 2. Overview of Scharf

Scharf is titled "System Using Green Light to Determine Parameters of a Cardiovascular System." Ex. 1025, code (54). Scharf describes a reflectance oximeter that uses two green light sources to detect oxygen saturation of hemoglobin in a volume of intravascular blood. *Id.* at 2:39–42.

<sup>&</sup>lt;sup>7</sup> It would appear that the reference character "82" on the right side of Figure 6 should read "83."

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Scharf's Figure 3 is reproduced below:

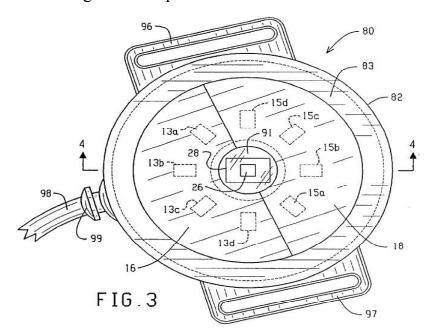


Figure 3 above shows a bottom plan view of an oximeter probe according to an embodiment. *Id.* at 3:40–41. The oximeter probe may include green lights formed of light emitting diodes (LEDs) 13, 15. *Id.* at 4:18–20. Scharf explains that, depending on the particular type of green light sources, green optical filters 16, 18 may be needed. *Id.* at 4:30–34.

# 3. Overview of Kotanagi

Kotanagi is titled "Biological Information Measuring Device." Ex. 1007, code (54). Kotanagi describes that a biological information measuring device can include a biological sensor including a body and a protrusion formed on the lower surface of the body. *Id.* at code (57). Kotanagi explains that the protrusion can be formed with a "curved surface." *Id.* ¶ 80.

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#### 4. Discussion

A principal feature of each of the independent claims of the '502 patent lies in the structure and arrangement of a "protrusion" located over four photodiodes arranged on an interior surface of a user-worn device. In particular, in claim 1 that feature reads as follows:

a protrusion comprising:

- a convex surface extending over the interior surface,
- a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface, and
- a plurality of windows, each of the windows extending across a different one of the openings[.]

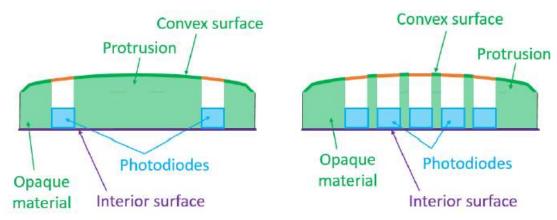
Ex. 1001, 45:11–19.

Thus, in claim 1, the protrusion feature requires a convex surface and multiple openings defined by an opaque surface and associated with a plurality of windows, with each window extending over a different opening. Independent claims 19 and 28 have similar requirements. Although not explicitly recited in claim 1, in the context of the '502 patent, the recited opaque surface is understood to aid in reducing "light piping" that reaches the photodiodes, which is an undesirable condition in which "light bypasses" the measurement site, e.g., human tissue, without being attenuated by that tissue. *See* Ex. 1001, 22:48–50; *see also* Prelim. Resp. 7–8 (description of light piping).<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> Independent claims 19 and 28, however, are explicit in reciting, respectively, that the opaque material is "configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue" (claim 19), and that that the "opaque surface [is] configured to reduce light piping" (claim 28).

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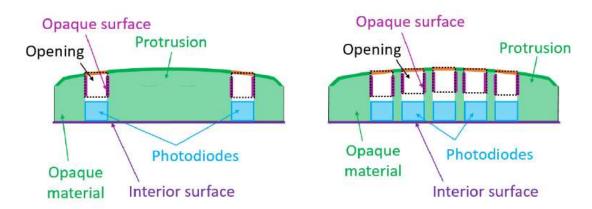
To arrive at the protrusion requirement in the claims, Petitioner presents composite or modified figures that Petitioner contends would have emerged from the teachings of Lumidigm and Kotanagi. Although Lumidigm does not present side views of the optical sensor that is illustrated in its Figures 6 and 7A (reproduced *supra*), Petitioner contends that based on the combined teachings of Lumidigm and Kotanagi, the following figures emerge:



Pet. 43–44 (citing Ex. 1003 ¶ 130). In Petitioner's and Dr. Kenny's view, and as depicted in the modified figure above, the application of Kotanagi's curved surface to each of Lumidigm's Figures 6 and 7A results in a "combination device" that "has a plurality of openings, one per photodiode, extending through the protrusion and positioned over the photodiodes." *Id.* at 45 (citing Ex. 1003 ¶ 133) (emphasis omitted). The basis of Petitioner's proposed ground of unpatentability, however, does not end there.

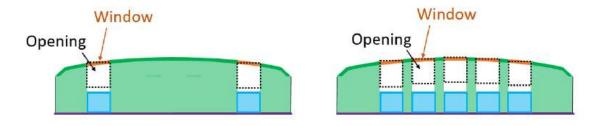
To account for the requirement, for instance, in claim 1 each opening is defined by an opaque surface, Petitioner offers the following additional "[c]omposite figures":

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Pet. 45. According to Petitioner, the combined teachings of Lumidigm and Kotanagi additionally would be configured to include distinct opaque surfaces (shown in purple in the composite figures above) that extend along some portion of the recessed openings over each photodiode. *Id.* 

Further still, in accounting for the requirements of the claims drawn to positioning different windows over each of the plurality of openings in the convex protrusion, Petitioner alleges that, in light of Scharf's teachings, the following further modified figures emerge:



*Id.* at 46.

Although it is certainly the case that an obviousness analysis may take into account the inferences and creative steps that a skilled artisan might glean from the teachings of the prior art (*see*, *e.g.*, *KSR*, 550 U.S. at 418), one must be cognizant that "hindsight is not an available analytical mechanism to show obviousness." *See In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1381 (Fed. Cir. 2007) (Newman, J., dissenting). Indeed, "we

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cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention." *See Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017). Without the guidance provided by the claims of the '502 patent, it is difficult to conclude that Petitioner's postulation as to a particular structure that results from combining the teachings of Lumidigm, Kotanagi, and Scharf is based on an objective assessment of what those teachings would have conveyed to a skilled artisan. It is clear from the Petition, however, that such structural configuration is necessary as the basis for Petitioner's approach to arriving at the structural requirements of the claims. <sup>9</sup>

At the outset, we share Patent Owner's view, and that of its declarant, Dr. Duckworth (Ex. 2002), that none of the prior art on which Petitioner relies discloses a convex protrusion with multiple openings or windows for multiple detectors. *See, e.g.*, Prelim. Resp 28–29; Ex. 2002 ¶ 76. As discussed above, Petitioner attempts to arrive at such structure through a proposed amalgamation of prior art teachings that must include, for instance, arranging a convex protrusion with multiple openings or separate glass windows over Lumidigm's optical sensors. In our view, however, Petitioner simply does not explain adequately why such configuration results from the actual teachings of the prior art.

Moreover, in an effort to next account for a convex shape of the protrusions and openings, Petitioner relies on Kotanagi's curved protrusion

<sup>&</sup>lt;sup>9</sup> Although Petitioner, in a footnote, generally contends that "other examples" of composite figure configurations "could be conceived" so as to render the challenged claims obvious, Petitioner does not provide further assessment or explanation in that regard. *See* Pet. 13 n.5. We find that general contention inadequately supported.

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as providing, for instance, "better contact" and be "more comfortable" for a user of Lumidigm's detector. *See, e.g.*, Pet. 28–29. Yet, consistent with the arguments advanced by Patent Owner and Dr. Duckworth, we are not satisfied that Petitioner adequately explains why a skilled artisan would have expected that such benefits would apply to the convoluted combination of modifications Petitioner proposes to arrive at the claimed invention. *See, e.g.*, Prelim. Resp. 41–50; Ex. 2002 ¶¶ 150–162. Nor has Petitioner explained adequately why a skilled artisan would have assessed that Petitioner's reasoning applies to a protrusion configured to have specific characteristics, e.g., multiple distinct openings and opaque lateral surfaces, intended to provide a particular function, i.e., reduction of light piping, that is unaffiliated with concerns of contact or comfort. *See, e.g.*, Prelim. Resp. 41–51; Ex. 2002 ¶¶ 167–179.

Further still, we share Patent Owner's skepticism (*see, e.g.*, Prelim. Resp. 69–72) that Petitioner's reliance on Scharf's teachings justifies Petitioner's theory that different windows would be placed over different openings within a convex protrusion. *See, e.g.*, Pet. 31–32. Although Petitioner expresses that "glass covers" generally are known in the art, in our view, Petitioner does not explain adequately why the particular teachings of Scharf on which Petitioner relies give rise to the specific window configuration required by the noted claims. *See id.* Dr. Duckworth's testimony supports Patent Owner's argument that Scharf's teachings applied to a combination of Lumidigm and Kotanagi do not convey reasonably to a skilled artisan the positioning of windows over the openings of a convex protrusion in the manner urged by Petitioner. *See, e.g.*, Ex. 2002 ¶¶ 189–195. Moreover, left wanting from Petitioner's theories is why a person of ordinary skill in the art would seek to apply Scharf's teachings as to a sensor

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face incorporating particular green optical filters 16, 18 intended to affect the output of light *emitters* (e.g., LEDs), so as to produce the particular placement of windows within different openings associated with the light *detectors* (i.e., photodiodes) of any combination of Lumidigm, Scharf, and Kotanagi.

We are mindful that Lumidigm discloses that its sensor head 32 (Fig. 2) may be formed of optically opaque material. *See* Ex. 1006, 8:1–4. We, however, take note of Patent Owner's arguments that Petitioner's proposed "opaque surface" structures illustrated in its composite figures from page 45 of the Petition (also reproduced *supra*) do not amount to such a surface that extends "through the protrusion" as required by each of claims 1, 19, and 28 or shows windows that are "lined with opaque material" as required by claim 19. *See* Prelim Resp. 56–57. In our view, those arguments credibly point out shortcomings in Petitioner's approach to account for the structure and characteristics of the opaque surface requirements of the claims.

Additionally, although Lumidigm discloses a desire to "minimize[s] the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue" (Ex. 1006, 8:4–7), we see some merit in Patent Owner's argument that such disclosure does not amount to avoiding light piping or detecting unattenuated light as is required by some, if not all, of the claims (*see* Prelim. Resp. 55–59). As discussed above, in the context of the '502 patent, "light piping" is understood as light that bypasses a measurement site. *See, e.g.*, Ex. 1001, 22:48–50. As Patent Owner and Dr. Duckworth note, Lumidigm seemingly discusses light that is reflected after tissue attenuation and does not express that its sensor is structured to address situations in which entirely unattenuated light, i.e., light that has

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entirely bypassed the measurement site, is intended to not be detected. *See* Prelim. Resp. 55–59; Ex. 2002 ¶¶ 183–185.

After consideration of the record before us, we find questionable Petitioner's and Dr. Kenny's assessment and reasoning as to what a skilled artisan would have understood from the teachings of Lumidigm, Scharf, and Kotanagi as proposed by Petitioner here. We find persuasive Patent Owner's arguments that Petitioner's and Dr. Kenny's assessments are grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art. *See, e.g.*, Prelim. Resp. 25–27. Dr. Duckworth's testimony that one of ordinary skill in the art would not have combined the teachings of the prior art in the manner advocated by Petitioner further supports Patent Owner's arguments. *See, e.g.*, Ex. 2002

Based on the record here, we conclude that Petitioner has not shown a reasonable likelihood of success based on any of the proposed grounds that involve the combined teachings of Lumidigm, Scharf, and Kotanagi. 10

#### III. CONCLUSION

Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.

## IV. ORDER

In consideration of the foregoing, it is

<sup>10</sup> The additional teachings of Tran are not offered by Petitioner to overcome the deficiencies discussed with respect to the combination of Lumidigm, Scharf, and Kotanagi.

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ORDERED that Petitioner's request for an *inter partes* review of claims 1–30 of the '502 patent Petition is *denied* and no trial is instituted.

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# **EXHIBIT 21**

Trials@uspto.gov

Paper 15

Tel: 571-272-7822 Entered: January 30, 2023

## UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC., Petitioner,

v.

MASIMO CORPORATION, Patent Owner.

IPR2022-01275 Patent 10,945,648 B2

Before JOSIAH C. COCKS, NEIL T. POWELL, and JAMES A TARTAL, *Administrative Patent Judges*.

POWELL, Administrative Patent Judge.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

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## I. INTRODUCTION

#### A. BACKGROUND

Apple Inc. ("Petitioner") filed a Petition for *inter partes* review of claims 1–30 of U.S. Patent No. 10,945,648 B2 (Ex. 1001, "the '648 patent"). Paper 3 ("Pet."). Masimo Corporation ("Patent Owner") filed a Preliminary Response. Paper 10 ("Prelim. Resp.").

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the Petition and any response thereto shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Considering the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner does not show a reasonable likelihood that at least one of the challenged claims is unpatentable. Accordingly, we do not institute *inter partes* review.

## B. RELATED PROCEEDINGS

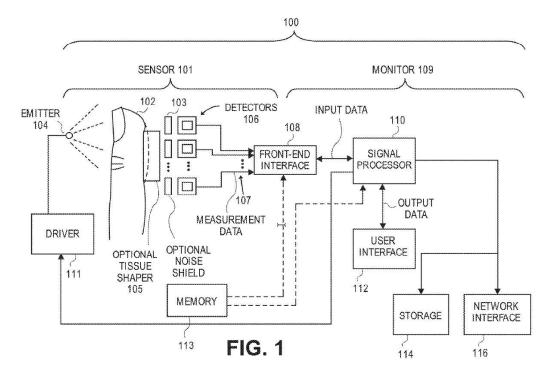
The parties note that the '648 patent is involved in *Masimo Corporation, et al. v. Apple Inc.*, ITC Inv. No. 337-TA-1276. Pet. 94; Paper 5, 1. Additionally, Patent Owner notes that the '648 patent is involved in Apple Inc. v. Masimo Corporation and Sound United, LLC, U.S. District Court for the District of Delaware, Case No. 1:22-cv-01378-MN. Paper 14, 1. The parties also identify a number of related *inter partes* review proceedings. Pet. 95; Paper 5, 3. Additionally, Patent Owner identifies a number of related patents, patent applications, and litigations involving related patents. Paper 5, 1–4.

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## C. THE '648 PATENT

The '648 patent discusses devices using spectroscopic analysis in patient monitoring. Ex. 1001, 2:14–19. These devices may have at least a light source that sends light into or off a measurement site, such as flesh with blood pulsing through it. *Id.* at 2:16–19. A photo-detection device detects attenuated light from the measurement site, generating a signal in response to the detected light. *Id.* at 2:19–22. The signal is processed by a signal processing device to produce data for monitoring a patient's condition. *Id.* at 2:25–28. For example, the signal processing device may indicate "a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, or other physiological parameters." *Id.* 

An example system for measuring one or more blood analytes noninvasively appears in Figure 1. *Id.* at 5:41–44. Figure 1 is reproduced below.



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Figure 1 shows data collection system 100, which includes sensor 101 and monitor 109. *Id.* at 11:51–53.

In the embodiment shown in Figure 1, sensor 101 "includes an emitter 104, a tissue shaper 105, a set of detectors 106, and a front-end interface 108." *Id.* at 11:63–65. Emitter 104 can send optical radiation to measurement site 102. *Id.* at 11:65–67. "[E]mitter 104 can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like." *Id.* at 12:1–4. Emitter 104 is driven by driver 111. *Id.* at 13:55–56. Monitor 109 may control driver 111, which can provide current pulses to emitter 104. *Id.* at 13:56–61.

Detectors 106 may capture and measure light generated by emitter 104 and attenuated or reflected from measurement site 102. *Id.* at 14:7–11. Responsive to the captured or measured light, detectors 106 can produce detector signal 107. *Id.* at 14:11–13. "[D]etectors 106 can be implemented using one or more photodiodes, phototransistors, or the like." *Id.* at 14:13–14.

The output of detectors 106 is adapted by front end interface 108. *Id.* at 14:31–33. "For example, the front end interface 108 can adapt a signal 107 received from one or more of the detectors 106 into a form that can be processed by the monitor 109." *Id.* at 14:33–36.

"[M]onitor 109 can include the signal processor 110 and a user interface, such as a display 112," as well as storage device 114, and network interface 116. *Id.* at 15:21–25. Signal processor 110 may have "processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors 106." *Id.* at 15:25–29.

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Signal processor 110 can control sensor 101's operation with signals, including an emitter control signal provided to driver 111 to control pulses from emitter 104. *Id.* at 15:34–39. "The user interface 112 can provide an output, e.g., on a display, for presentation to a user of the data collection system 100." *Id.* at 15:51–53. "The various software and/or firmware applications can be stored in the storage device 114, which can be executed by the signal processor 110 or another processor of the monitor 109." *Id.* at 16:2–5. Network interface 116 may enable monitor 109 to share data and communicate with other devices. *Id.* at 16:5–11.

"[M]ore detailed examples of embodiments of a sensor" appear in Figures 3A through 3C. *Id.* at 18:33–34. Figure 3A is reproduced below.

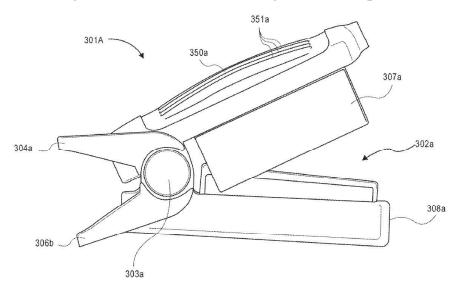


FIG. 3A

Figure 3A shows sensor 301a, which "is a clothespin-shaped clip sensor that includes an enclosure 302a for receiving a patient's finger. The enclosure 302a is formed by an upper section or emitter shell 304a, which is

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pivotably connected with a lower section or detector shell 306a." <sup>1</sup> *Id.* at 18:37–42. Another view of sensor 301a appears in Figure 3C, which is reproduced below.

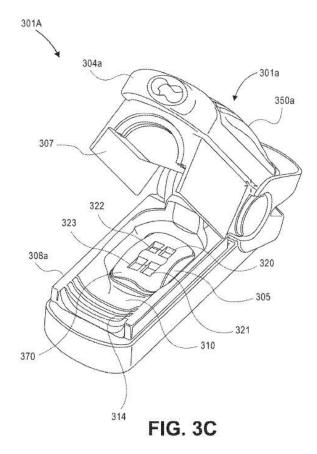


Figure 3C shows sensor 301a's finger bed 310. *Id.* at 19:7–8.

Finger bed 310 may have a generally curved surface suited for receiving flesh, e.g., a human digit. *Id.* at 19:8–10. Ridges 314 on finger bed 310 may help hold a patient's finger to finger bed 310, which can promote accurate spectroscopic analysis. *Id.* at 19:10–17.

Finger bed 310 can also comprise protrusion 305. *Id.* at 19:22–23. Protrusion 305 may be a convex bump. *Id.* at 21:18–19. Protrusion 305

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<sup>&</sup>lt;sup>1</sup> In this passage, it appears that "detector shell 306a" should read "detector shell 308a."

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comprises measurement site contact area 370. *Id.* at 19:23–25. Contact area 370 has windows 320, 321, 322, and 323. *Id.* at 19:31–33. "[W]indows 320, 321, 322, and 323 can be made from materials, such as plastic or glass." *Id.* at 19:45–46.

In an embodiment, the location of windows 320, 321, 322, and 323 may mirror the location of photodetectors, allowing light from a measurement site to reach the photodetectors through windows 320, 321, 322, and 323. *Id.* at 19:33–41. Additionally, "[i]n an embodiment, the photodetectors can be positioned within or directly beneath the protrusion." *Id.* at 20:18–19. The '648 patent shows this in Figure 3E, which is reproduced below.

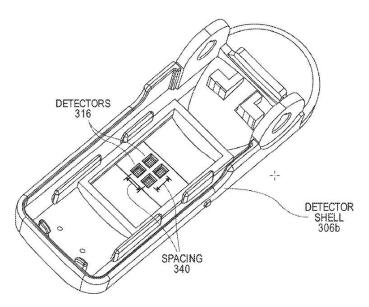


FIG. 3E

Figure 3E "illustrates a perspective view of an example noninvasive sensor detector shell including example detectors." *Id.* at 5:56–58.

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Specifically, Figure 3E shows detectors 316. *Id.* at 22:28–32. "The detectors 316 can have a predetermined spacing 340 from each other, or a spatial relationship among one another that results in a spatial configuration." *Id.* at 22:33–35.

## D. ILLUSTRATIVE CLAIM

Of the challenged claims, claims 1, 6, 8, and 20 are independent. Each of claims 2–5, 7, 9–19, and 21–30 depends, directly or indirectly, from one of independent claims 1, 6, 8, and 20. Claim 1 is illustrative and is reproduced below with certain reformatting:<sup>2</sup>

- 1. [1pre] A user-worn device configured to non-invasively determine measurements of physiological parameter of a user, the user-worn device comprising:
  - [1a] a plurality of light emitting diodes (LEDs);
  - [1b] four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user;
  - [1c-1] a protrusion comprising a convex surface and
  - [1c-2] a plurality of openings extending through the protrusion, the openings arranged over the photodiodes and
  - [1c-3] configured to allow light to pass through the protrusion to the photodiodes; and
  - one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.

Ex. 1001, 44:51–65.

E. EVIDENCE

Petitioner relies on the following evidence:

<sup>&</sup>lt;sup>2</sup> We have added the same carriage returns and labels that Petitioner applies to different portions of claim 1. *See* Pet. vi.

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- (1) U.S. Patent No. 6,801,799 B2, issued Oct. 5, 2004 ("Mendelson-799") (Ex. 1006).
- (2) U.S. Patent Application Publication No. 2002/0188210 A1, published Dec. 12, 2002 ("Aizawa") (Ex. 1007).
- (3) U.S. Patent Application Publication No. 2001/0056243 A1, published Dec. 27, 2001 ("Ohsaki") (Ex. 1008).
- (4) U.S. Patent Application Publication No. 2007/0093786, published Apr. 26, 2007 ("Goldsmith") (Ex. 1009).
- (5) U.S. Patent Application Publication No. 2006/0211924, published Sep. 21, 2006 ("Dalke") (Ex. 1010).
- (6) U.S. Patent No. 6,330,468 B1, issued Dec. 11, 2001 ("Scharf") (Ex. 1011).
- (7) Published International Patent Application No. WO 2005/092182 A1, published Oct. 6, 2005 ("Kotanagi") (Ex. 1016).
- (8) U.S. Patent No. 3,789,601, issued Feb. 5, 1974 ("Bergey") (Ex. 1021).
- (9) U.S. Patent No. 5,952,084, issued Sep. 14, 1999 ("Anderson") (Ex. 1023).
  - (10) Declaration of Thomas W. Kenny, Ph.D. (Ex. 1003).

Patent Owner relies on the declaration of R. James Duckworth, Ph.D. (Ex. 2002).

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F. ASSERTED GROUND OF UNPATENTABILITY
Petitioner challenges the patentability of claims 1–30 of the '648 patent on the following grounds (Pet. 6–7):

Claims Challenged	35 U.S.C. §	Reference(s)
1, 2, 4, 5	103	Mendelson-799, Aizawa, Ohsaki
3, 20, 21–30	103	Mendelson-799, Aizawa, Ohsaki, Scharf
6–16, 19	103	Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke, Goldsmith
17	103	Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke, Goldsmith, Bergey
18	103	Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke, Goldsmith, Anderson
1, 2, 4, 5	103	Mendelson-799, Aizawa, Kotanagi
3, 20, 21–30	103	Mendelson-799, Aizawa, Kotanagi, Scharf
6–16, 19	103	Mendelson-799, Aizawa, Kotanagi, Scharf, Dalke, Goldsmith
17	103	Mendelson-799, Aizawa, Kotanagi, Scharf, Dalke, Goldsmith, Bergey
18	103	Mendelson-799, Aizawa, Kotanagi, Scharf, Dalke, Goldsmith, Anderson

## II. ANALYSIS

## A. LEVEL OF ORDINARY SKILL

## Petitioner contends that

[a] person of ordinary skill in the art relating to the subject matter of the '648 Patent as of July 3, 2008 ("POSITA") would have been a person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in

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combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. APPLE-1003, ¶¶40-41. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline. *Id*.

Pet. 3–4. Patent Owner does not dispute Petitioner's description of a person of ordinary skill in the art. *See* Prelim. Resp. 10. For purposes of deciding whether Petitioner has demonstrated a reasonable likelihood of prevailing, we adopt Petitioner's definition of a person of ordinary skill in the art, which we find consistent with the '648 patent and the asserted prior art.

## B. CLAIM CONSTRUCTION

In an *inter partes* review proceeding, a claim of a patent is construed using the same standard used in federal district court, including construing the claim in accordance with the ordinary and customary meaning of the claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b) (2020). According to the applicable standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art in question at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (citations omitted). Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. America Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner argues that "[n]o formal claim constructions are necessary in this proceeding." Pet. 3. Patent Owner contends we "should give the

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claim terms their ordinary and customary meaning, consistent with the specification, as a [person of ordinary skill in the art] would understand them." Prelim. Resp. 10. We do not discern a need to construe any claim language expressly in order to determine whether Petitioner demonstrates a reasonable likelihood of prevailing.

C. ALLEGED OBVIOUSNESS OF CLAIMS 1, 2, 4, AND 5 OVER MENDELSON-799, AIZAWA, AND OHSAKI

## 1. Overview of Mendelson-799

Mendelson-799 is a U.S. patent titled "Pulse Oximeter and Method of Operation," and discloses a sensor for non-invasive measurement of a blood parameter, which includes a sensor housing, a radiation source, and a detector. Ex. 1006, codes (54), (57).

Figure 7 of Mendelson-799 is reproduced below.

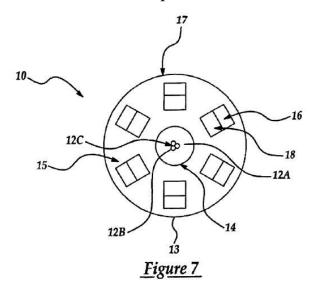


Figure 7 above illustrates optical sensor 10 with sensor housing 17 and light source 12, which includes three light emitting elements 12a, 12b, 12c. *Id.* at 9:22–28. Optical sensor 10 includes an array of discrete detectors, i.e., "far" detectors 16 and "near" detectors 18, "arranged in two concentric ring-like arrangements... surrounding the light emitting

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elements." *Id.* at 9:29–34. Sensor housing 17 accommodates the light source and detectors. *Id.* at 9:34–35.

## 2. Overview of Aizawa

Aizawa is a U.S. patent application publication titled "Pulse Wave Sensor and Pulse Rate Detector," and discloses a pulse wave sensor that detects light output from a light emitting diode and reflected from a patient's artery. Ex. 1007, codes (54), (57).

Figure 1(a) of Aizawa is reproduced below.

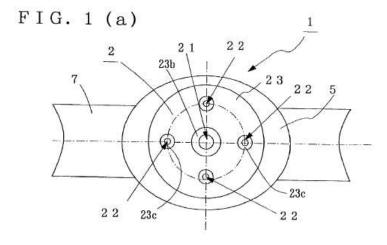
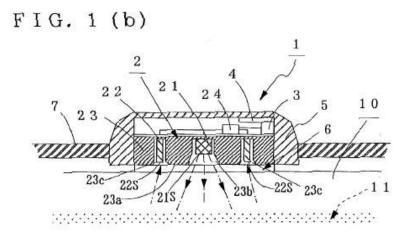


Figure 1(a) is a plan view of a pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(a), pulse wave sensor 2 includes light emitting diode ("LED") 21, four photodetectors 22 symmetrically disposed around LED 21, and holder 23 for storing LED 21 and photodetectors 22. *Id.* Aizawa discloses that, "to further improve detection efficiency, . . . the number of the photodetectors 22 may be increased." *Id.* ¶ 32, Fig. 4(a). "The same effect can be obtained when the number of photodetectors 22 is 1 and a plurality of light emitting diodes 21 are disposed around the photodetector 22." *Id.* ¶ 33.

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Figure 1(b) of Aizawa is reproduced below.



## 3. Overview of Ohsaki

Ohsaki is a U.S. patent application publication titled "Wristwatch-type Human Pulse Wave Sensor Attached on Back Side of User's Wrist," and discloses an optical sensor for detecting a pulse wave of a human body. Ex. 1008, code (54), ¶ 3.

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Figure 1 of Ohsaki is reproduced below.

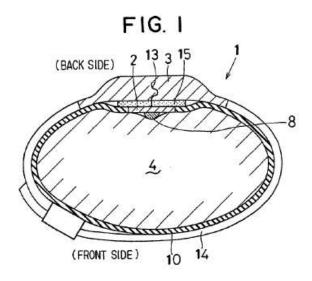
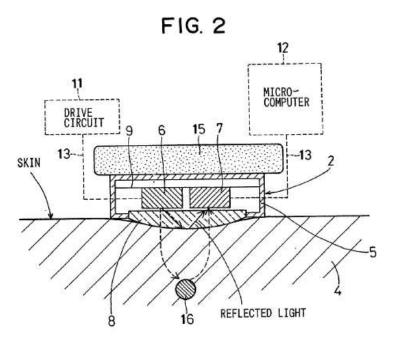


Figure 1 illustrates a cross-sectional view of pulse wave sensor 1 attached on the back side of user's wrist 4. *Id.* ¶¶ 12, 16. Pulse wave sensor 1 includes detecting element 2 and sensor body 3. *Id.* ¶ 16.

Figure 2 of Ohsaki, reproduced below, illustrates further detail of detecting element 2.



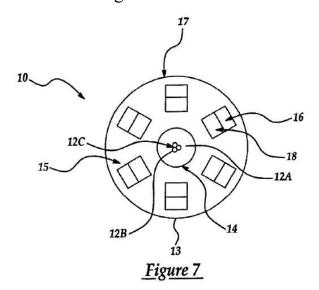
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Figure 2 illustrates a mechanism for detecting a pulse wave. *Id.* ¶ 13. Detecting element 2 includes package 5, light emitting element 6, light receiving element 7, and translucent board 8. *Id.* ¶ 17. Light emitting element 6 and light receiving element 7 are arranged on circuit board 9 inside package 5. *Id.* ¶¶ 17, 19.

## 4. Discussion

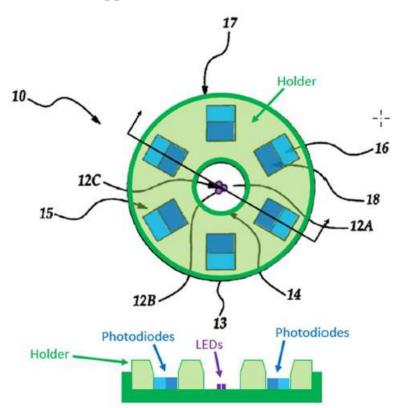
A principal feature of independent claim 1 lies in the structure and arrangement of a "protrusion" located over four photodiodes arranged on a user-worn device. In this respect, claim 8 recites "a protrusion comprising a convex surface and a plurality of openings extending through the protrusion, the openings arranged over the photodiodes and configured to allow light to pass through the protrusion to the photodiodes." Ex. 1001, 44:58–62.

To arrive at the protrusion requirement in the claims, Petitioner presents a series of composite or modified figures that Petitioner contends would have emerged from the teachings of the prior art, specifically here, Mendelson-799, Aizawa, and Ohsaki. At the outset, we reproduce again Mendelson-799's unmodified Figure 7:



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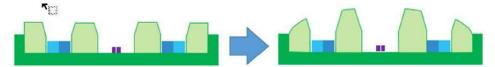
Figure 7 above illustrates Mendelson-799's optical sensor 10 with light sources 12a, 12b, and 12c and an "array of discrete detectors" (16 and 18) accommodated within sensor housing 17. Ex. 1006, 9:22–35. Although Mendelson-799 does not present a side view of the optical sensor illustrated in its Figure 7 (reproduced *supra*), Petitioner contends that Mendelson-799's Figure 7, when modified by the teachings of Aizawa to incorporate an opaque "holder," would appear as follows:



Pet. 19 (citing Ex. 1003 ¶ 54). In Petitioner's and Dr. Kenny's view, and as depicted in the modified figure above, the application of a holder from Aizawa onto Mendelson's optical sensor is asserted to result in multiple additional interior portions that extend in a manner so as to constitute a "protrusion" with multiple openings. *See, e.g., id.* at 20. The basis of Petitioner's proposed ground of unpatentability, however, does not end

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there. To account for the claim requirement pertaining to a convex surface, Petitioner proceeds to Ohsaki's teachings, and specifically its disclosure of translucent board 8 with convex surface, shown, for instance, in Ohsaki's Figure 2 (reproduce *supra*). Although, as Patent Owner notes, Ohsaki's board 8 is a singular structure that is translucent without openings (*see* Prelim. Resp. 38), Petitioner and Dr. Kenny are of the view that applying Ohsaki's teachings to Mendelson-799 and Aizawa, results in a further reconfiguration of the opaque holder said to arise from Mendeslon-799's and Aizawa's teachings as follows:



Id. at 24–25 (citing Ex.  $1003 \, \P \, 62$ ). Petitioner and Dr. Kenny generally contend that the above-reproduced figure on the right results from the combined teachings of Mendelson-799, Aizawa, and Ohsaki as a matter of simply being "use of a known technique to improve similar devices in the same way." Id. at 25 (citing Ex.  $1003 \, \P \, 64$ ).

Although it is certainly the case that an obviousness analysis may take into account the inferences and creative steps that a skilled artisan might glean from the teachings of the prior art (see, e.g., KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007)), one must be cognizant that "hindsight is not an available analytical mechanism to show obviousness." See In re Omeprazole Patent Litig., 483 F.3d 1364, 1381 (Fed. Cir. 2007) (Newman, J., dissenting). Indeed, "we cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention." See Metalcraft of Mayville, Inc. v. The Toro Co., 848 F.3d 1358, 1367 (Fed. Cir. 2017). Without the guidance provided by the claims of the

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'648 patent, it is difficult to conclude that Petitioner's postulation as to a particular structure that results from combining the teachings of Mendelson-799, Aizawa, and Ohsaki is based on an objective assessment of what those teachings would have conveyed to a skilled artisan. It is clear from the Petition, however, that such structural configuration is necessary as the basis for Petitioner's approach to arriving at the structural requirements of the claims.<sup>3</sup>

At the outset, we share Patent Owner's view, and that of its declarant, Dr. Duckworth (Ex. 2002), that none of the prior art on which Petitioner relies discloses a convex protrusion with multiple openings for multiple detectors. *See, e.g.*, Prelim. Resp 35; Ex. 2002 ¶ 76. The proposed amalgamation of prior art teachings includes, for instance, arranging a "holder" from Aizawa into a configuration that, for ill explained reasons, forms protruded portions of that holder containing multiple openings associated with photodetectors of Mendelson-799's optical sensor in an attempt to satisfy the structural requirements of the claim. *See, e.g.*, Pet. 19–20. In our view, however, Petitioner simply does not explain adequately why such configuration with respect to Mendelson-799's optical sensor results from the actual teachings of the prior art.

Further still, in an effort to next account for a convex shape of the protrusions and openings, Petitioner must rely on Ohsaki's convex translucent board under the premise that Ohsaki's board shape would

<sup>3</sup> Although Petitioner, in a footnote, generally contends that "other examples" of composite figure configurations "could be conceived" so as to render the challenged claims obvious, Petitioner does not provide further assessment or explanation in that regard. *See* Pet. 19 n.4. We find that general contention unavailing.

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"improve adhesion" or provide "improved user comfort" for the detector formed from a combination of Mendelson-799 and Aizawa. *See, e.g.*Pet. 21–26. Yet, consistent with the arguments advanced by Patent Owner and Dr. Duckworth, we are not satisfied that Petitioner adequately explains why a skilled artisan would have expected that such benefits would apply to the convoluted combination of modifications Petitioner proposes to arrive at the claimed invention. *See, e.g.*, Prelim. Resp. 28–33, 59–61, 67–69;

Ex. 2002 ¶¶ 109–111, 122–126. Nor has Petitioner explained adequately why a skilled artisan would have assessed that Petitioner's reasoning applies to a protrusion configured to have specific characteristics, e.g., multiple distinct openings, that are unaffiliated with adhesion or comfort. *See, e.g.*, Prelim. Resp. 28–33, 59–61, 67–69; Ex. 2002 ¶¶ 109–111, 122–126.

On the record before us here, we find questionable Petitioner's and Dr. Kenny's assessment and reasoning as to what a skilled artisan would have understood from the teachings of Mendelson-799, Aizawa, and Ohsaki as proposed by Petitioner here. We find persuasive Patent Owner's arguments that Petitioner's and Dr. Kenny's assessments are grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art. *See, e.g.*, Prelim. Resp. 30–34. Dr. Duckworth's testimony that one of ordinary skill in the art would not have combined the teachings of the prior art in the manner advocated by Petitioner further supports Patent Owner's arguments. *See, e.g.*, Ex. 2002 ¶¶ 109–111, 122–126.

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D. ALLEGED OBVIOUSNESS OF CLAIMS 3, 20 AND 21–30 OVER MENDELSON-799, AIZAWA, OHSAKI, AND SCHARF

## 1. Overview of Scharf

Scharf is titled "System Using Green Light to Determine Parameters of a Cardiovascular System." Ex. 1011, code (54). Scharf describes a reflectance oximeter that uses two green light sources to detect oxygen saturation of hemoglobin in a volume of intravascular blood. *Id.* at 2:39–42.

Scharf's Figure 3 is reproduced below:

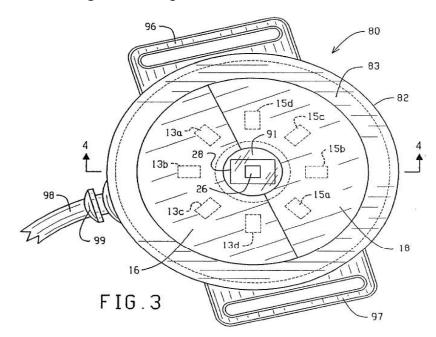


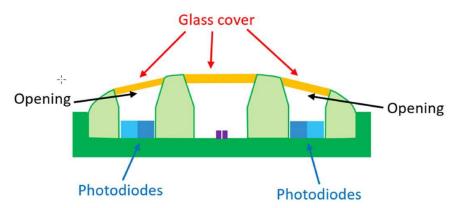
Figure 3 above shows a bottom plan view of an oximeter probe according to an embodiment. *Id.* at 3:40–41. The oximeter probe may include green lights formed of light emitting diodes (LEDs) 13, 15. *Id.* at 4:18–20. Scharf explains that, depending on the particular type of green light sources, green optical filters 16, 18 may be needed. *Id.* at 4:30–34.

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## 2. Discussion

In this challenge, the Petition cites Mendelson-799, Aizawa, and Ohsaki to address limitations of claims 3, 20, and 21–30 that are similar to limitations in claims 1, 2, 4, and 5. In many instances, Petitioner's arguments regarding the limitations of claims 3, 20, and 21–30 cite its arguments regarding similar limitations of claims 1, 2, 4, and 5. *See, e.g.*, Pet. 40–41 (for multiple limitations of independent claim 20, citing Petition's challenge of claim 1 based on Mendelson-799, Aizawa, and Ohsaki).

Petitioner cites Scharf when addressing certain limitations related to windows over photodiodes. *E.g.*, Pet. 42–44. Petitioner alleges that adding Scharf's teachings to those of Mendelson-799, Aizawa, and Ohsaki produces the configuration in the following illustration:



Pet. 39–40 (citing Ex. 1003 ¶¶ 91–92). The reasoning for that further modified figure based on Scharf's teachings is premised on a desire to protect electronic components "from contaminants like dirt and moisture." Id. at 40.

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Petitioner's arguments about Scharf do not cure the deficiencies discussed above in Section II.C.4 in the combination of Mendelson-799, Aizawa, and Ohsaki.

Additionally, we find unpersuasive Petitioner's arguments about the modifications that a person of ordinary skill in the art allegedly would have made based on Scharf. We share Patent Owner's skepticism that the teachings of the prior art, and specifically Scharf, justifies Petitioner's theory that separate windows would be placed over different openings within a convex protrusion so as to provide a general benefit of protecting electronics "from contaminants like dirt and moisture." *See*, *e.g.*, Pet. 40. Although Petitioner expresses that a "glass cover" generally may provide such protections, Petitioner does not explain adequately why, even if true, that the teachings on which Petitioner relies give rise to the particular window configuration required by the claims. *See id.* We also find credible Dr. Duckworth's testimony that Scharf's teachings applied to a combination of Mendelson, Aizawa, and Ohsaki do not convey reasonably to a skilled artisan the positioning of windows over the openings of a convex protrusion in the manner urged by Petitioner. *See*, *e.g.*, Ex. 2002 ¶¶ 90–93.

We do not find that Petitioner has demonstrated a reasonable likelihood of prevailing on its challenge of any of claims 3, 20, and 21–30 as allegedly obvious over Mendelson-799, Aizawa, Ohsaki, and Scharf.

- E. Alleged Obviousness of Claims 6–16 and 19 over Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke, and Goldsmith
  - 1. Overview of Dalke

Dalke notes that "[s]pectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a

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solution." Ex.  $1010 \, \P \, 4$ . Dalke elaborates that "[a] practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO<sub>2</sub>) and pulse rate." *Id.* ¶ 5.

Dalke discloses a physiological sensor with light emitting sources that can transmit light with multiple wavelengths. Id. at code (57). After body tissue attenuates the emitted light, a detector responds to the light. Id. In pulse oximetry, the sensor generally "has light emitting diodes (LEDs) that transmit optical radiation or red and infrared wavelengths into a tissue site" and a detector "responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site." Id. ¶ 5. Dalke discusses a particular example of a sensor in connection with Figure 3. Figure 3 is reproduced below.

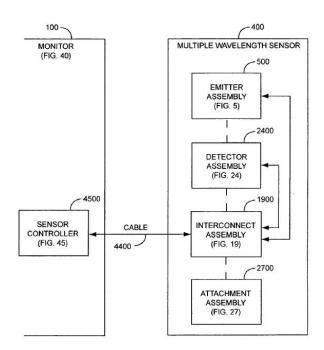


FIG. 3

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Figure 3 "is a general block diagram of a multiple wavelength sensor and sensor control."  $Id. \ 12$ .

Figure 3 shows sensor assembly 400, which includes "an emitter assembly 500, a detector assembly 2400, an interconnect assembly 1900 and an attachment assembly 2400." *Id.* ¶ 58. In response to drive signals received from monitor 100's sensor controller 4500, emitter assembly 500 sends optical radiation with multiple wavelengths into a tissue site. *Id.* "The detector assembly 2400 provides a sensor signal to the monitor 100 via the cable 4400 in response to optical radiation received after attenuation by the tissue site." *Id.* Dalke discusses emitter array 500 further in connection with Figure 5. Figure 5 is reproduced below.

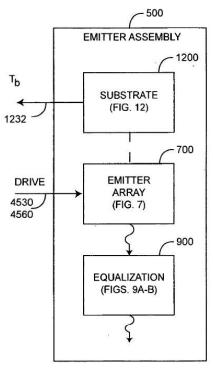


Figure 5 shows "an emitter assembly 500 having an emitter array 700, a substrate 1200, and equalization 900." *Id.* ¶ 61.

Emitter array 700 includes multiple light emitting sources that can transmit multiple wavelengths of optical radiation. *Id.* "LEDs within the

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emitter array 700 may be grouped according to output intensity or wavelength or both." Id. ¶ 75.

Dalke also discloses "one embodiment of a substrate 1200 configured to provide thermal conductivity between an emitter array 700... and a thermistor 1540." *Id.* ¶ 81. Dalke discusses this in connection with Figures 13–18. *Id.* Figures 15 and 16 are reproduced below.

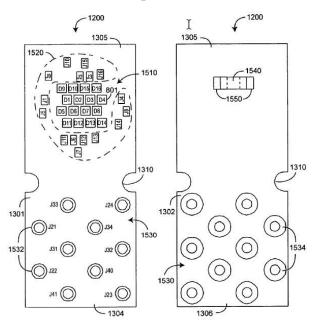


FIG. 15 FIG. 16

Figures 15 and 16 "are top and bottom component layout views of an emitter substrate embodiment." *Id.* ¶23. Measuring the resistance of thermistor 1540 allows determining the bulk temperature of LEDs mounted on substrate 1200. *Id.* ¶81.

## 2. Overview of Goldsmith

Goldsmith discloses "[a]n infusion system that includes a watch controller device and a communication system to transmit the communications from the watch controller device to an infusion device pump that controls delivery of fluids to the user's body." Ex. 1009, code

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(57). Specifically, Goldsmith discloses using these devices for ascertaining how much insulin to supply. *Id.* Goldsmith discusses one embodiment in connection with Figure 9A. Figure 9A is reproduced below.

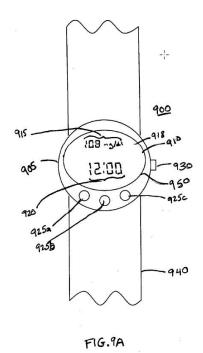


Figure 9A "is a front view of a combined watch and controller device according to an embodiment."  $Id. \, \P \, 30$ .

Specifically, Figure 9A shows combined watch and controller device 900, which includes housing 905 and wrist band 940. *Id.* ¶ 85. "The housing 905 may include a transparent member 950 on the front side over a display 910." *Id.* Additionally, "[t]he watch controller device may include one or more input devices 925a, 925b, 925c, 930 on the controller device housing, such as keys, buttons or the like, for the user to input data or commands." *Id.* Display 910 may show the time, as well as "whatever information and/or graph is being displayed on the infusion device display or the analyte monitor display." *Id.* ¶ 86. For example, the display may indicate glucose levels. *Id.* 

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## 3. Discussion

In this challenge, the Petition cites Mendelson-799, Aizawa, and Ohsaki to address limitations of claims 6–16 and 19 that are similar to limitations in claims 1, 2, 4, and 5. In many instances, Petitioner's arguments regarding the limitations of claims 6–16 and 19 cite its arguments regarding similar limitations of claims 1, 2, 4, and 5. *See*, *e.g.*, Pet. 63, 68 (for multiple limitations of independent claim 6, citing Petition's challenge of claim 1 based on Mendelson-799, Aizawa, and Ohsaki).

Petitioner cites Dalke as disclosing "[i]n addition to photodiodes, . . . a thermistor." *Id.* at 52–53. Petitioner also cites Dalke as "expressly recogniz[ing] that '*any number of LED groups*' may be used." Pet. 58 (citing Ex. 1010 ¶ 75). Accordingly, Petitioner argues, "simply doubling the LED cluster provided in Mendelson-799 . . . would have been obvious to a [person of ordinary skill in the art]." *Id*.

Petitioner relies on Goldsmith as disclosing "a touchscreen display." Pet. 53. Petitioner cites Goldsmith's "touch screen display," for example, when addressing claim 10's recitation of "a user interface including a touch-screen display configured to display indicia responsive to the measurements of the physiological parameter." Pet. 73.

Petitioner's arguments about Dalke and Goldsmith do not cure the deficiencies, discussed above in Section II.C.4, in its claim challenges based on Mendelson-799, Aizawa, and Ohsaki. We do not find that Petitioner has demonstrated a reasonable likelihood of prevailing on its challenge of any of claims 6–16 and 19 as allegedly obvious over Mendelson-799, Aizawa, Ohsaki, Dalke, and Goldsmith.

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F. ALLEGED OBVIOUSNESS OF CLAIM 17 OVER MENDELSON-799, AIZAWA, OHSAKI, SCHARF, DALKE, GOLDSMITH, AND BERGEY

## 1. Overview of Bergey

Bergey discloses "a solid state electronic wristwatch with no moving parts." Ex. 1021, code [57]. Bergey discusses an embodiment in connection with Figure 1. Figure 1 is reproduced below.

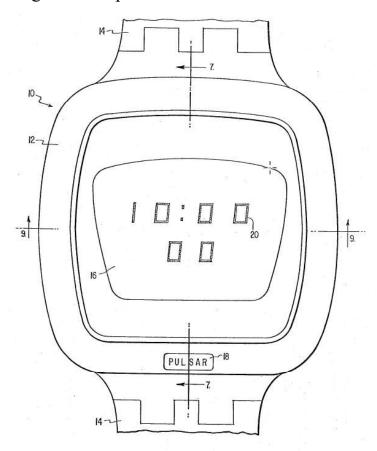


Figure 1 shows watch 10, which includes watch case 12 attached to wristwatch bracelet 14. *Id.* at 3:57–62. Bergey provides additional details regarding the construction of watch 10 in Figure 9. Figure 9 is reproduced below.

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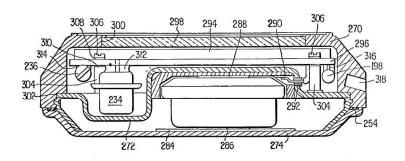


FIG. 9

Figure 9 "is a cross section . . . taken along line 9-9 of [Figure] 1." *Id.* at 3:46–47.

"The watch case 12 comprises a front plate 270, an inner cover 272, and a removable back plate 274." *Id.* at 8:32–34. Bergey explains that "the electronics 294 is hermetically sealed all the way around between inner cover 272 and front plate 270. This hermetic seal acts as protection to the electronics and also prevents condensation of water vapor on the filter 298." *Id.* at 9:22–26.

## 2. Discussion

Claim 17 depends from independent claim 8 and recites "wherein the housing hermetically seals at least a portion of an interior of the user-worn device." Ex. 1001, 46:26–28. Addressing this, Petitioner argues that Bergey discloses a hermetically sealed watch. Pet. 85. Petitioner contends that

a [person of ordinary skill in the art] would have been motivated to look to prior art such as Bergey, for example, to obtain the advantages described by Bergey (e.g., to hermetically seal the components to produce a waterproof, shockproof device) by modifying the Mendelson-799-Aizawa-Ohsaki-Scharf-Dalke-Goldsmith device such that the sensor housing hermetically seals at least a portion of an interior of the user-worn device, as taught by Bergey, to protect the electronics and prevent "condensation of water vapor" inside of the case.

Id. at 86.

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Petitioner's arguments regarding Bergey do not cure the deficiencies, discussed above in Sections II.C.4 and II.E.3, in Petitioner's challenge of independent claim 8 as allegedly obvious over Mendelson-799, Aizawa, Ohsaki, Dalke, and Goldsmith. We do not find Petitioner has demonstrated a reasonable likelihood of establishing obviousness of claim 17 over Mendelson-799, Aizawa, Ohsaki, Dalke, Goldsmith, and Bergey.

G. ALLEGED OBVIOUSNESS OF CLAIM 18 OVER MENDELSON-799, AIZAWA, OHSAKI, SCHARF, DALKE, GOLDSMITH, AND ANDERSON

## 1. Overview of Anderson

Anderson relates to "transparent substrates, in particular glass substrates, which are provided with coatings composed of one or more thin films . . . designed to give specific properties to the substrates which bear them, for example, thermal, optical, or electrical properties." Ex. 1023, 1:5–10. Anderson explains that an "anti-reflection coating" works to decrease a substrate's light reflection factor, thereby "increasing its light transmission factor." *Id.* at 1:22–28. This increases the visibility of objects behind the substrate. *Id.* at 1:28–30. An anti-reflection coating may be a stack of certain materials. *Id.* at 5:1–6. Additionally, including a conductive material film in the stack can provide an anti-static function. *Id.* at 5:32–38.

## 2. Discussion

Claim 18 recites "[t]he user-worn device of claim 8, wherein the windows comprise a conductive material." Ex. 1001, 46:29–30. Addressing this, Petitioner alleges that Anderson discloses a coating with "a film of a conductive material" in its coating, in particular, 'a material of the doped metal oxide type, such as tin-doped indium oxide ITO." Pet. 88. Based on this and arguments that it would have been obvious to add Anderson's

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disclosures to those of Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke, and Goldsmith, Petitioner argues that "[i]n the combination, *the windows include* an anti-reflection coating containing a 'conductive material,' such as 'a material of the doped metal oxide type, such as tin-doped indium oxide ITO,' as taught by Anderson, on at least one surface." *Id.* at 91. Petitioner's arguments and evidence regarding Anderson do not cure the deficiencies, discussed above in Section II.C.4, in Petitioner's assertions that independent claim 8 would have been obvious over Lumidigm, Scharf, and Kotanagi. Petitioner has not demonstrated a reasonable likelihood of establishing that claim 18 would have been obvious over Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke, and Goldsmith. We do not find Petitioner has demonstrated a reasonable likelihood of establishing obviousness of claim 18 over Mendelson-799, Aizawa, Ohsaki, Scharf, Dalke, Goldsmith, and Anderson.

H. GROUNDS BASED ON MENDELSON-799, AIZAWA, AND KOTANAGI Petitioner also contends that all of the challenged claims are rendered obvious based largely on the combined teachings of Mendelson-799, Aizawa, and Kotanagi. Patent Owner does not agree.

## 1. Overview of Kotanagi

Kotanagi is titled "Biological Information Measuring Device." Ex. 1016, code (54). Kotanagi describes that a biological information measuring device can include a biological sensor including a body and a protrusion formed on the lower surface of the body. *Id.* at code (57). Kotanagi explains that the protrusion can be formed with a "curved surface." *Id.* at ¶ 80.

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## 2. Discussion

Petitioner proposes that all of the challenged claims are unpatentable based, in whole or in part, on the combined teachings of Mendelson-799, Aizawa, and Kotanagi. Kotanagi's teachings are advanced by Petitioner as being analogous to, or alternative of, those of Ohsaki. *See, e.g.*, Pet. 93–96. In particular, Petitioner specifies that it applies Kotanagi's teachings for "the same reasons" as was proposed for the grounds including Ohsaki and that Kotanagi provides "additional/alternative motivations" to apply a convex protrusion in conjunction with the combined teachings of Mendelson-799 and Aizawa. *See, e.g.*, *id.* at 95.

In our view, Petitioner's proposed grounds of unpatentability for the challenged claims fare no better based on Kotanagi's teachings than they did for those grounds based on Ohsaki's teachings. For the same reasons discussed above, we conclude that Petitioner has not shown a reasonable likelihood of success in connection with any of its proposed grounds that involve the combined teachings of Mendelson-799, Aizawa, and Kotanagi. <sup>4</sup>

## III. CONCLUSION

Because we determine that the information presented in the record does not establish there is a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim of the patent '648 patent, we do not institute an *inter partes* review.

## IV. ORDER

For the reasons given, it is:

<sup>4</sup> Here, too, Petitioner's citations to Scharf, Dalke, Goldsmith, Bergey, and Anderson do not overcome the deficiencies identified with respect to the combination of Mendelson-799, Aizawa, and Kotanagi.

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ORDERED that the Petition is denied as to all challenged claims of the '648 patent and no trial is instituted.

## For PETITIONER:

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# **EXHIBIT 22**

Trials@uspto.gov

Paper 15

Tel: 571-272-7822 Entered: January 30, 2023

## UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC., Petitioner,

v.

MASIMO CORPORATION, Patent Owner.

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Before JOSIAH C. COCKS, NEIL T. POWELL, and JAMES A TARTAL, *Administrative Patent Judges*.

POWELL, Administrative Patent Judge.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

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## I. INTRODUCTION

#### A. BACKGROUND

Apple Inc. ("Petitioner") filed a Petition for *inter partes* review of claims 1–30 of U.S. Patent No. 10,945,648 B2 (Ex. 1001, "the '648 patent"). Paper 2 ("Pet."). Masimo Corporation ("Patent Owner") filed a Preliminary Response. Paper 10 ("Prelim. Resp.").

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the Petition and any response thereto shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Considering the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner does not show a reasonable likelihood that at least one of the challenged claims is unpatentable. Accordingly, we do not institute *inter partes* review.

## B. RELATED PROCEEDINGS

The parties note that the '648 patent is involved in *Masimo Corporation*, et al. v. Apple Inc., ITC Inv. No. 337-TA-1276. Pet. 94; Paper 5, 1. Apple Inc. v. Masimo Corporation and Sound United, LLC, U.S. District Court for the District of Delaware, Case No. 1:22-cv-01378-MN. Paper 14, 1. The parties also identify a number of related *inter partes* review proceedings. Pet. 95; Paper 5, 3. Additionally, Patent Owner identifies a number of related patents, patent applications, and litigations involving related patents. Paper 5, 1–4.

## C. THE '648 PATENT

The '648 patent discusses devices using spectroscopic analysis in patient monitoring. Ex. 1001, 2:14–19. These devices may have at least a

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light source that sends light into or off a measurement site, such as flesh with blood pulsing through it. *Id.* at 2:16–19. A photo-detection device detects attenuated light from the measurement site, generating a signal in response to the detected light. *Id.* at 2:19–22. The signal is processed by a signal processing device to produce data for monitoring a patient's condition. *Id.* at 2:25–28. For example, the signal processing device may indicate "a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, or other physiological parameters." *Id.* 

An example system for measuring one or more blood analytes noninvasively appears in Figure 1. *Id.* at 5:41–44. Figure 1 is reproduced below.

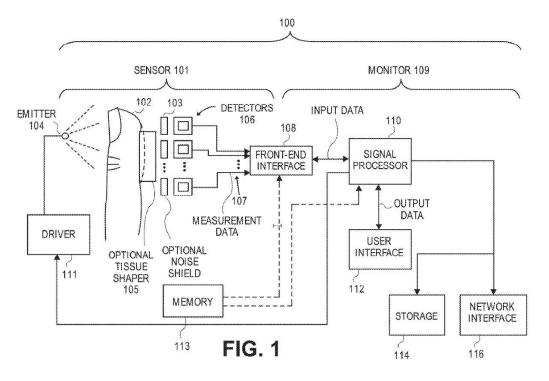


Figure 1 shows data collection system 100, which includes sensor 101 and monitor 109. *Id.* at 11:51–53.

In the embodiment shown in Figure 1, sensor 101 "includes an emitter 104, a tissue shaper 105, a set of detectors 106, and a front-end

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interface 108." *Id.* at 11:63–65. Emitter 104 can send optical radiation to measurement site 102. *Id.* at 11:65–67. "[E]mitter 104 can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like." *Id.* at 12:1–4. Emitter 104 is driven by driver 111. *Id.* at 13:55–56. Monitor 109 may control driver 111, which can provide current pulses to emitter 104. *Id.* at 13:56–61.

Detectors 106 may capture and measure light generated by emitter 104 and attenuated or reflected from measurement site 102. *Id.* at 14:7–11. Responsive to the captured or measured light, detectors 106 can produce detector signal 107. *Id.* at 14:11–13. "[D]etectors 106 can be implemented using one or more photodiodes, phototransistors, or the like." *Id.* at 14:13–14.

The output of detectors 106 is adapted by front end interface 108. *Id.* at 14:31–33. "For example, the front end interface 108 can adapt a signal 107 received from one or more of the detectors 106 into a form that can be processed by the monitor 109." *Id.* at 14:33–36.

"[M]onitor 109 can include the signal processor 110 and a user interface, such as a display 112," as well as storage device 114, and network interface 116. *Id.* at 15:21–25. Signal processor 110 may have "processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors 106." *Id.* at 15:25–29. Signal processor 110 can control sensor 101's operation with signals, including an emitter control signal provided to driver 111 to control pulses from emitter 104. *Id.* at 15:34–39. "The user interface 112 can provide an output, e.g., on a display, for presentation to a user of the data collection

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system 100." *Id.* at 15:51–53. "The various software and/or firmware applications can be stored in the storage device 114, which can be executed by the signal processor 110 or another processor of the monitor 109." *Id.* at 16:2–5. Network interface 116 may enable monitor 109 to share data and communicate with other devices. *Id.* at 16:5–11.

"[M]ore detailed examples of embodiments of a sensor" appear in Figures 3A through 3C. *Id.* at 18:33–34. Figure 3A is reproduced below.

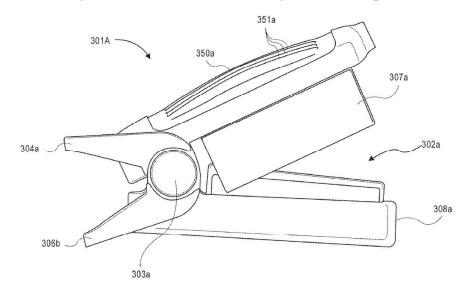


FIG. 3A

Figure 3A shows sensor 301a, which "is a clothespin-shaped clip sensor that includes an enclosure 302a for receiving a patient's finger. The enclosure 302a is formed by an upper section or emitter shell 304a, which is pivotably connected with a lower section or detector shell 306a." <sup>1</sup> *Id.* at 18:37–42. Another view of sensor 301a appears in Figure 3C, which is reproduced below.

<sup>&</sup>lt;sup>1</sup> In this passage, it appears that "detector shell 306a" should read "detector shell 308a."

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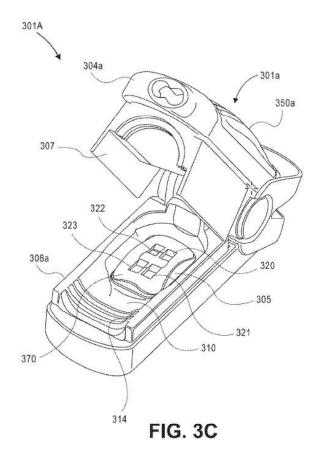


Figure 3C shows sensor 301a's finger bed 310. *Id.* at 19:7–8.

Finger bed 310 may have a generally curved surface suited for receiving flesh, e.g., a human digit. *Id.* at 19:8–10. Ridges 314 on finger bed 310 may help hold a patient's finger to finger bed 310, which can promote accurate spectroscopic analysis. *Id.* at 19:10–17.

Finger bed 310 can also comprise protrusion 305. *Id.* at 19:22–23. Protrusion 305 may be a convex bump. *Id.* at 21:18–19. Protrusion 305 comprises measurement site contact area 370. *Id.* at 19:23–25. Contact area 370 has windows 320, 321, 322, and 323. *Id.* at 19:31–33. "[W]indows 320, 321, 322, and 323 can be made from materials, such as plastic or glass." *Id.* at 19:45–46.

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In an embodiment, the location of windows 320, 321, 322, and 323 may mirror the location of photodetectors, allowing light from a measurement site to reach the photodetectors through windows 320, 321, 322, and 323. *Id.* at 19:33–41. Additionally, "[i]n an embodiment, the photodetectors can be positioned within or directly beneath the protrusion." *Id.* at 20:18–19. The '648 patent shows this in Figure 3E, which is reproduced below.

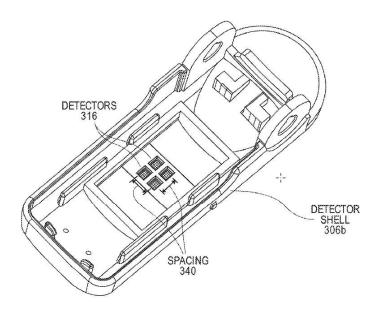


FIG. 3E

Figure 3E "illustrates a perspective view of an example noninvasive sensor detector shell including example detectors." *Id.* at 5:56–58.

Specifically, Figure 3E shows detectors 316. *Id.* at 22:28–32. "The detectors 316 can have a predetermined spacing 340 from each other, or a spatial relationship among one another that results in a spatial configuration." *Id.* at 22:33–35.

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#### D. ILLUSTRATIVE CLAIM

Of the challenged claims, claims 1, 6, 8, and 20 are independent. Each of claims 2–5, 7, 9–19, and 21–30 depends, directly or indirectly, from one of independent claims 1, 6, 8, and 20. Claim 8 is illustrative and is reproduced below with certain reformatting:<sup>2</sup>

- 1. [8pre] A user-worn device configured to non-invasively determine measurements of physiological parameter of a user, the user-worn device comprising:
  - [8a] a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;
  - [8b] a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
  - [8c] four photodiodes;
  - [8d] a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;
  - [8e] a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;
  - [8f] a separate optically transparent window extending across each of the openings;
  - [8g] one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user;
  - [8h] a housing; and
  - [8i] a strap configured to position the housing proximate tissue of the user when the device is worn.

<sup>&</sup>lt;sup>2</sup> We have added the same labels that Petitioner uses to identify different portions of claim 8. *See* Pet. vi–vii.

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Ex. 1001, 45:45–46:3.

#### E. EVIDENCE

Petitioner relies on the following evidence:

- (1) U.S. Patent No. 7,620,212 B1, issued Nov. 17, 2009 ("Lumidigm") (Ex. 1006).
- (2) Published International Patent Application No. WO 2005/092182 A1, published Oct. 6, 2005 ("Kotanagi") (Ex. 1007).
- (3) U.S. Patent No. 9,820,658 B2, issued Nov. 21, 2017 ("Tran") (Ex. 1008).
- (4) U.S. Patent No. 9,001,047 B2, issued Apr. 7, 2015 ("Forstall") (Ex. 1017).
- (5) U.S. Patent No. 5,952,084, issued Sep. 14, 1999 ("Anderson") (Ex. 1018).
- (6) U.S. Patent No. 6,330,468 B1, issued Dec. 11, 2001 ("Scharf") (Ex. 1025).
- (7) Declaration of Thomas W. Kenny, Ph.D. (Ex. 1003).Patent Owner relies on the declaration of R. James Duckworth, Ph.D. (Ex. 2002).
- F. ASSERTED GROUND OF UNPATENTABILITY
  Petitioner challenges the patentability of claims 1–30 of the '648 patent on the following grounds (Pet. 4):

Claims Challenged	35 U.S.C. §	Reference(s)		
8, 9	103	Lumidigm, Scharf, Kotanagi		
1–7, 10, 12–17, 19, 20–30	103	Lumidigm, Scharf, Kotanagi, Tran		

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Claims Challenged	35 U.S.C. §	Reference(s)
11	103	Lumidigm, Scharf, Kotanagi, Tran, Forstall
18	103	Lumidigm, Scharf, Kotanagi, Anderson

#### II. ANALYSIS

#### A. LEVEL OF ORDINARY SKILL

#### Petitioner contends that

[a] person of ordinary skill in the art relating to the subject matter of the '648 Patent as of July 3, 2008 ("POSITA") would have been a person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. APPLE-1003, ¶¶40-41. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline. *Id*.

Pet. 2. Patent Owner does not dispute Petitioner's description of a person of ordinary skill in the art. *See* Prelim. Resp. 10. For purposes of deciding whether Petitioner has demonstrated a reasonable likelihood of prevailing, we adopt Petitioner's definition of a person of ordinary skill in the art, which we find consistent with the '648 patent and the asserted prior art.

#### B. CLAIM CONSTRUCTION

In an *inter partes* review proceeding, a claim of a patent is construed using the same standard used in federal district court, including construing the claim in accordance with the ordinary and customary meaning of the

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claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b) (2020). According to the applicable standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art in question at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (citations omitted). Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. America Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner argues that "[n]o formal claim constructions are necessary in this proceeding." Pet. 3. Patent Owner contends we "should give the claim terms their ordinary and customary meaning, consistent with the specification, as a [person of ordinary skill in the art] would understand them." Prelim. Resp. 10. We do not discern a need to construe any claim language expressly in order to determine whether Petitioner demonstrates a reasonable likelihood of prevailing.

- C. ALLEGED OBVIOUSNESS OF CLAIMS 8 AND 9 OVER LUMIDIGM, SCHARF, AND KOTANAGI
  - 1. Overview of Lumidigm

Lumidigm is titled "Electro-Optical Sensor." Ex. 1006, code (54). Lumidigm's Abstract is reproduced below:

Methods and systems are provided that extend the functionality of electro-optical sensors. A device has a multiple light sources, a light detector, and a processor configured to operate the light sources and the light detector to perform distinct functions. At least one of the distinct functions includes a biometric identification function in which light is propagated

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from the plurality of light sources through presented material. The propagated light is received with the light detector, with the presented material being identified from the received light. Another of the distinct functions includes a nonidentification function performed with the light sources and the light detector.

*Id.* at code (57).

Lumidigm's Figure 2 is reproduced below:

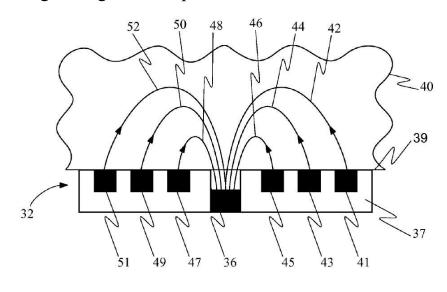
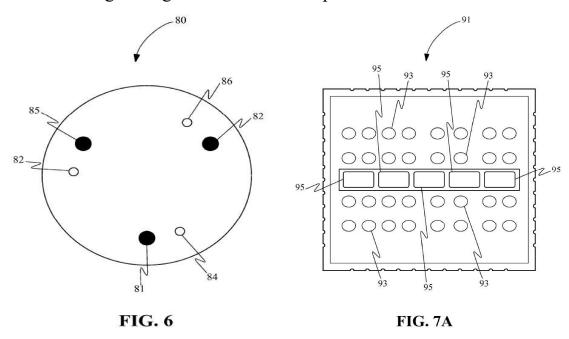


FIG. 2

Figure 2 above depicts a "cross-sectional view of a biometric sensor element couple to a tissue surface showing multiple mean optical paths." *Id.* at 4:45–47. Sensor head 32 includes light sources 41, 43, 45, 47, 49, 51 and detector 36. *Id.* at 7: 5–10. Optical paths 42, 44, 46, 48, 50, 52 show light passing through tissue 40. *Id.* Sensor head 32 is formed of optically opaque material 37.

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Lumidigm's Figures 6 and 7A are reproduced below:



Figures 6 and 7A above illustrate top-views of biometric sensors according to two embodiments of the invention. *Id.* at 4:60–67. In Figure 6, light sensor 80 includes light sources 82, 84, 86 positioned relative to detectors 81, 83, 85. *Id.* at 9:14–16.<sup>3</sup> In Figure 7A, sensor 91 includes two rows of light sources 93 and one row of detectors 95. *Id.* at 9:27–30.

## 2. Overview of Scharf

Scharf is titled "System Using Green Light to Determine Parameters of a Cardiovascular System." Ex. 1025, code (54). Scharf describes a reflectance oximeter that uses two green light sources to detect oxygen saturation of hemoglobin in a volume of intravascular blood. *Id.* at 2:39–42.

<sup>&</sup>lt;sup>3</sup> It would appear that the reference character "82" on the right side of Figure 6 should read "83."

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Scharf's Figure 3 is reproduced below:

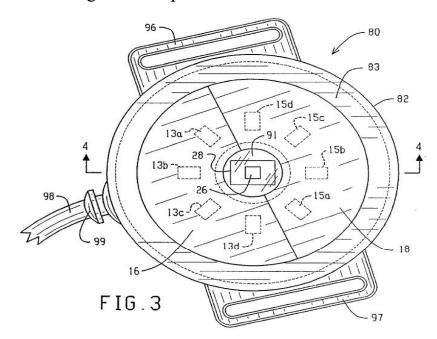


Figure 3 above shows a bottom plan view of an oximeter probe according to an embodiment. *Id.* at 3:40–41. The oximeter probe may include green lights formed of light emitting diodes (LEDs) 13, 15. *Id.* at 4:18–20. Scharf explains that, depending on the particular type of green light sources, green optical filters 16, 18 may be needed. *Id.* at 4:30–34.

## 3. Overview of Kotanagi

Kotanagi is titled "Biological Information Measuring Device." Ex. 1007, code (54). Kotanagi describes that a biological information measuring device can include a biological sensor including a body and a protrusion formed on the lower surface of the body. *Id.* at code (57). Kotanagi explains that the protrusion can be formed with a "curved surface." *Id.* ¶ 80.

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#### 4. Discussion

A principal feature of independent claim 8 lies in the structure and arrangement of a "protrusion" located over four photodiodes arranged on a user-worn device. In this respect, claim 8 recites:

a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;

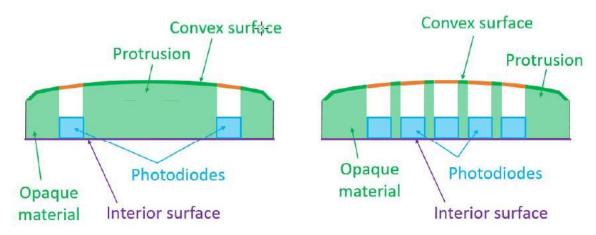
a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes; [and]

a separate optically transparent window extending across each of the openings.

Ex. 1001, 45:57–64. Thus claim 8 requires an at least partially opaque protrusion feature with a convex surface, multiple openings position over multiple photodiodes, and optically transparent windows across the openings.

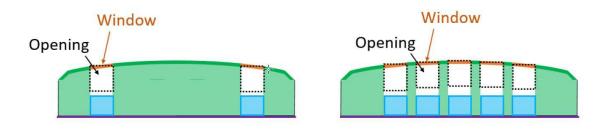
To arrive at the protrusion requirement in the claims, Petitioner presents composite or modified figures that Petitioner contends would have emerged from the teachings of Lumidigm and Kotanagi. Although Lumidigm does not present side views of the optical sensor that is illustrated in its Figures 6 and 7A (reproduced *supra*), Petitioner contends that based on the combined teachings of Lumidigm and Kotanagi, the following figures emerge:

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Pet. 41–42 (citing Ex. 1003 ¶ 125). In Petitioner's and Dr. Kenny's view, and as depicted in the modified figure above, the application of Kotanagi's curved surface to each of Lumidigm's Figures 6 and 7A results in a "combination device" with a protrusion and "a plurality of openings, one per photodiode, extending through the protrusion and positioned over the photodiodes." *Id.* at 42 (citing Ex. 1003 ¶ 127) (emphasis omitted). The basis of Petitioner's proposed ground of unpatentability, however, does not end there.

Additionally, in accounting for the claim language drawn to positioning a separate window across each opening in the convex protrusion, Petitioner alleges that, in light of Scharf's teachings, the following further modified figures emerge:



*Id.* at 43–44.

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Although it is certainly the case that an obviousness analysis may take into account the inferences and creative steps that a skilled artisan might glean from the teachings of the prior art (see, e.g., KSR Int'l Co. v. Teleflex *Inc.*, 550 U.S. 398, 418 (2007)), one must be cognizant that "hindsight is not an available analytical mechanism to show obviousness." See In re Omeprazole Patent Litig., 483 F.3d 1364, 1381 (Fed. Cir. 2007) (Newman, J., dissenting). Indeed, "we cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention." See Metalcraft of Mayville, Inc. v. The Toro Co., 848 F.3d 1358, 1367 (Fed. Cir. 2017). Without the guidance provided by the claims of the '648 patent, it is difficult to conclude that Petitioner's postulation as to a particular structure that results from combining the teachings of Lumidigm, Kotanagi, and Scharf is based on an objective assessment of what those teachings would have conveyed to a skilled artisan. It is clear from the Petition, however, that such structural configuration is necessary as the basis for Petitioner's approach to arriving at the structural requirements of the claims.4

At the outset, we share Patent Owner's view, and that of its declarant, Dr. Duckworth (Ex. 2002), that none of the prior art on which Petitioner relies discloses a convex protrusion with multiple openings or windows for multiple detectors. *See*, *e.g.*, Prelim. Resp 28–29; Ex. 2002 ¶ 76. As discussed above, Petitioner attempts to arrive at such structure through a

<sup>4</sup> Although Petitioner, in a footnote, generally contends that "other examples" of composite figure configurations "could be conceived" so as to render the challenged claims obvious, Petitioner does not provide further assessment or explanation in that regard. *See* Pet. 14 n.5. We find that general contention inadequately supported.

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proposed amalgamation of prior art teachings that must include, for instance, arranging a convex protrusion with multiple openings and separate glass windows over Lumidigm's optical sensors. In our view, however, Petitioner simply does not explain adequately why such configuration results from the actual teachings of the prior art.

Moreover, in an effort to next account for a convex shape of the protrusions and openings, Petitioner relies on Kotanagi's curved protrusion as providing, for instance, "better contact" and be "more comfortable" for a user of Lumidigm's detector. *See*, *e.g.*, Pet. 29–30. Yet, consistent with the arguments advanced by Patent Owner and Dr. Duckworth, we are not satisfied that Petitioner adequately explains why a skilled artisan would have expected that such benefits would apply to the convoluted combination of modifications Petitioner proposes to arrive at the claimed invention. *See*, *e.g.*, Prelim. Resp. 43–52; Ex. 2002 ¶¶ 163–175. Nor has Petitioner explained adequately why a skilled artisan would have assessed that Petitioner's reasoning applies to a protrusion configured to have specific characteristics, e.g., at least partly having opaque material and having multiple distinct openings, that are unaffiliated with concerns of contact or comfort. *See*, *e.g.*, Prelim. Resp. 43–52; Ex. 2002 ¶¶ 163–175.

Further still, we share Patent Owner's skepticism (*see*, *e.g.*, Prelim. Resp. 63–67) that Petitioner's reliance on Scharf's teachings justifies Petitioner's theory that separate glass coverings or windows would be placed over different openings within a convex protrusion. *See*, *e.g.*, Pet. 32–33. Although Petitioner expresses that "glass covers" generally are known in the art, in our view, Petitioner does not explain adequately why the particular teachings of Scharf on which Petitioner relies give rise to the specific

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window configuration required by the noted claims. *See id.* Dr. Duckworth's testimony supports Patent Owner's argument that Scharf's teachings applied to a combination of Lumidigm and Kotanagi do not convey reasonably to a skilled artisan the positioning of windows over the openings of a convex protrusion in the manner urged by Petitioner. *See, e.g.*, Ex. 2002  $\P$  179–185.

After consideration of the record before us, we find questionable Petitioner's and Dr. Kenny's assessment and reasoning as to what a skilled artisan would have understood from the teachings of Lumidigm, Scharf, and Kotanagi as proposed by Petitioner here. We find persuasive Patent Owner's arguments that Petitioner's and Dr. Kenny's assessments are grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art. *See, e.g.*, Prelim. Resp. 26–28. Dr. Duckworth's testimony that one of ordinary skill in the art would not have combined the teachings of the prior art in the manner advocated by Petitioner further supports Patent Owner's arguments. *See, e.g.*, Ex. 2002

Based on the record here, we conclude Petitioner has not shown a reasonable likelihood of demonstrating obviousness of either claim 8 or 9 in view of Lumidigm, Scharf, and Kotanagi.

- D. ALLEGED OBVIOUSNESS OF CLAIMS 1–7, 10, 12–17, 19, AND 20–30 OVER LUMIDIGM, SCHARF, KOTANAGI, AND TRAN
  - 1. Overview of Tran

Tran discusses patient monitoring in connection with Figure 1. Ex. 1008, 8:42. Figure 1 is reproduced below.

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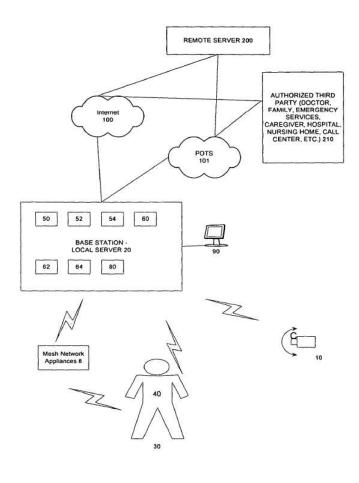


FIG. 1

Figure 1 shows "an exemplary system for monitoring a person." *Id.* at 8:7–8.

The system may include appliances 8, which can be one of multiple portable physiological transducer, such a s blood pressure monitor, heart rate monitor, weight scale, thermometer, spirometer, single or multiple lead electrocardiograph (ECG), a pulse oximeter, a body fat monitor, a cholesterol monitor a signal from a medicine cabinet, a signal from a drug container, a signal from a commonly used appliance such as a refrigerator/stove/oven/washer, or a signal from an exercise machine such as a heart rate.

Id. at 8:49-58.

Tran explains that "one appliance is a patient monitoring device that can be worn by a patient." *Id.* at 8:59–60. Tran adds that patient 30 "may

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wear one or more wearable patient monitoring appliances such as wrist-watches or clip on devices or electronic jewelry to monitor the patient." *Id.* at 9:66–10:1. "One wearable appliance such as a wrist-watch includes sensors 40, for example devices for sensing ECG, EKG, blood pressure, sugar level, among others." *Id.* at 10:1–4. Tran discusses an example in connection with Figure 6A. Figure 6A is reproduced below.

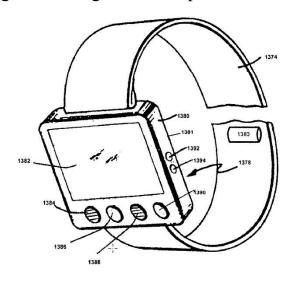


FIG. 6A

Figure 6A "shows an exemplary wrist-watch based assistance device." *Id.* at 8:16–17. The device comprises a wrist-watch sized case 1380 attached to a wrist band 1374. *Id.* at 46:5–6. "The housing 1380 contains the processor and associated peripherals to provide the human-machine interface." *Id.* at 49:11–13. The front section of housing 1380 includes display 1382, speaker 1384, push-button switch 1386, microphone 1388, and push-button switch 1390. *Id.* at 49:13–17.

#### 2. Discussion

Petitioner's challenge of claims 1–5, 6, 7, 10, 12–17, 19, and 20–30 based on Lumidigm, Scharf, Kotanagi, and Tran builds from its challenge of

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independent claim 8 based on Lumidigm, Scharf, and Kotanagi.<sup>5</sup> Pet. 49–87. When addressing the limitations of independent claims 1, 6, and 20, the Petition generally refers back to its treatment of the limitations of independent claim 8 based on Lumidigm, Scharf, and Kotanagi. E.g., Pet. 57–65, 70–73, 81–82. Petitioner adds arguments and evidence regarding Tran to address certain limitations not present in independent claim 8, such as independent claim 1's requirement for "one or more processors configured to . . . determine measurements of oxygen saturation of the user." Ex. 1001, 44:63–65; Pet. 65. The evidence and arguments Petitioner adds to address claims 1–5, 6, 7, 10, 12–17, 19, and 20–30 do not cure the deficiencies, discussed above in Section II.C.4, in Petitioner's assertions that claims 8 and 9 would have been obvious over Lumidigm, Scharf, and Kotanagi. Petitioner has not demonstrated a reasonable likelihood of establishing that any of claims 1–5, 6, 7, 10, 12–17, 19, and 20–30 would have been obvious over Lumidigm, Scharf, Kotanagi, and Tran.

<sup>&</sup>lt;sup>5</sup> In contrast to page 4 of the Petition, Page 49 of the Petition includes claim 18 among those that Petitioner contends is allegedly obvious over Lumidigm, Scharf, Kotanagi, and Tran. But the section of the Petition discussing the details of the challenge based on Lumidigm, Scharf, Kotanagi, and Tran does not further discuss claim 18. *See* Pet. 49–87. Accordingly, the statement on page 49 of the Petition that claim 18 would have been obvious over Lumidigm, Scharf, Kotanagi, and Tran appears to be a typographical error.

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E. ALLEGED OBVIOUSNESS OF CLAIM 11 OVER LUMIDIGM, SCHARF, KOTANAGI, TRAN, AND FORSTALL

#### 1. Overview of Forstall

Forstall discloses a portable multifunction device that, in some embodiments, "has a touch-sensitive display (also known as a 'touch screen') with a graphical user interface (GUI), one or more processors, memory and one or more modules, programs, or sets of instructions stored in the memory for performing multiple functions." Ex. 1017, 2:36–43. Forstall's Figure 2 is reproduced below.

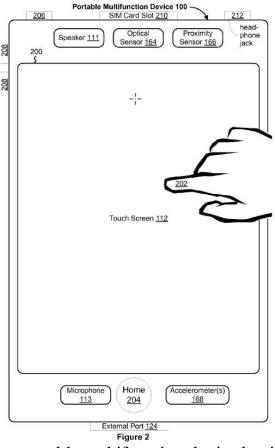


Figure 2 "illustrates a portable multifunction device having a touch screen in accordance with some embodiments." *Id.* at 4:7–8.

In particular, Figure 2 shows portable multifunction device 100, which includes touch screen 112. *Id.* at 14:66–15:1. Inside user interface

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200, touch screen 112 may present one or more graphics. *Id.* at 15:1–2. "[A] user may select one or more of the graphics by making contact or touching the graphics, for example, with one or more fingers 202." *Id.* at 15:3–5. Forestall explains that

[a] graphical user interface one a portable multifunction device with a rectangular touch screen display with a portrait view and a landscape view comprises a first mode of an application that is displayed in the portrait view and a second mode of the application that is displayed in the landscape view.

# Id. at 18:59–64. Forstall adds that mode changes based on device orientation make the device easier to use because the user does not have to navigate through one or more display screens to get to a desired second mode or remember how to perform such navigation. Rather, the user changes the orientation of the device (e.g., from vertical or portrait to horizontal or landscape) to transition an application to a corresponding second mode.

*Id.* at 19:4–10.

#### 2. Discussion

Claim 11 depends indirectly from independent claim 8. Ex. 1001, 46:4–12. Petitioner's challenge of claim 11 based on Lumidigm, Scharf, Kotanagi, Tran, and Forstall cites Forstall because it allegedly "discloses a portable device with a touch screen user interface with orientation capability." Pet. 87. Based on this and arguments that it would have been obvious to add Forstall's disclosures to those of Lumidigm, Scharf, Kotanagi, and Tran, Petitioner argues that "[t]he *orientation of the user interface* of the touch screen of the combination device (e.g., orientation from vertical/portrait to horizontal/landscape)) is dependent on *user input* (e.g., the user changes the orientation of the device)." *Id.* at 89. Petitioner's arguments and evidence regarding the alleged obviousness of claim 11 over

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Lumidigm, Scharf, Kotanagi, Tran, and Forstall do not cure the deficiencies, discussed above in Section II.C.4, in Petitioner's assertions that independent claim 8 would have been obvious over Lumidigm, Scharf, and Kotanagi. Petitioner has not demonstrated a reasonable likelihood of establishing that claim 11 would have been obvious over Lumidigm, Scharf, Kotanagi, Tran, and Forstall.

F. ALLEGED OBVIOUSNESS OF CLAIM 18 OVER LUMIDIGM, SCHARF, KOTANAGI, AND ANDERSON

### 1. Overview of Anderson

Anderson relates to "transparent substrates, in particular glass substrates, which are provided with coatings composed of one or more thin films . . . designed to give specific properties to the substrates which bear them, for example, thermal, optical, or electrical properties." Ex. 1018, 1:5–10. Anderson explains that an "anti-reflection coating" works to decrease a substrate's light reflection factor, thereby "increasing its light transmission factor." *Id.* at 1:22–28. This increases the visibility of objects behind the substrate. *Id.* at 1:28–30. An anti-reflection coating may be a stack of certain materials. *Id.* at 5:1–6. Additionally, including a conductive material film in the stack can provide an anti-static function. *Id.* at 5:32–38.

#### 2. Discussion

Claim 18 recites "[t]he user-worn device of claim 8, wherein the windows comprise a conductive material." Ex. 1001, 46:29–30. Petitioner's challenge of claim 18 based on Lumidigm, Scharf, Kotanagi, and Anderson cites Anderson because it allegedly discloses a coating with "a film of a conductive material" *e.g.*, 'a material of the doped metal oxide type, such as tin-doped indium oxide ITO." Pet. 90. Based on this and arguments that it

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would have been obvious to add Anderson's disclosures to those of Lumidigm, Scharf, and Kotanagi, Petitioner argues that "[i]n the combination, *the windows include* an anti-reflection coating containing a 'conductive material,' such as 'a material of the doped metal oxide type, such as tin-doped indium oxide ITO,' as taught by Anderson, on at least one surface." *Id.* at 92. Petitioner's arguments and evidence regarding the alleged obviousness of claim 18 over Lumidigm, Scharf, Kotanagi, and Anderson do not cure the deficiencies, discussed above in Section II.C.4, in Petitioner's assertions that independent claim 8 would have been obvious over Lumidigm, Scharf, and Kotanagi. Petitioner has not demonstrated a reasonable likelihood of establishing that claim 18 would have been obvious over Lumidigm, Scharf, Kotanagi, and Anderson.

#### III. CONCLUSION

Because we determine that the information presented in the record does not establish there is a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim of the patent '648 patent, we do not institute an *inter partes* review.

#### IV. ORDER

For the reasons given, it is:

ORDERED that the Petition is *denied* as to all challenged claims of the '648 patent and no trial is instituted.

> IPR2022-01276 Patent 10,945,648 B2

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# **EXHIBIT 23**





North Campus Research Complex 2800 Plymouth Road Ann Arbor, MI, 48109 (734) 647-4751

Via Electronic Submission

The Honorable Katherine M. Hiner Acting Secretary U.S. International Trade Commission 500 E Street, S.W. Washington, D.C. 20436

Re: Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv.

No. 337-TA-1276

To the International Trade Commission,

My name is Kevin Ward, MD and I am a Professor in the Departments of Emergency Medicine and Biomedical Engineering at the University of Michigan. I am also a Fellow of both the American College of Emergency Physicians and the American Academy of Emergency Medicine. Prior to joining the University of Michigan in 2012, I was Professor and Associate Chair of Emergency Medicine at Virginia Commonwealth University (VCU) were I also founded and directed the VCU Reanimation Engineering Science Center (VCURES). I write in response to the Commission's solicitations of comments regarding the public interest, and in support of the suggested remedial orders against Apple. For the reasons described below, in my opinion, the Apple Watches with pulse oximetry capabilities does not benefit public welfare, and certainly not in any manner that outweighs the public's interest in strong intellectual property rights.

My research interests span the field of critical illness and injury ranging from combat casualty care to the intensive care unit. I develop and leverage broad platform technologies capable of use throughout all echelons of care of the critically ill and injured as well as in all age groups including noninvasive monitors and predictive algorithms. My work has been funded by the NIH, Department of Defense, NSF, and industry. My passion is in creating programs which encourage true integration across the disciplines of medicine, engineering, data sciences, and entrepreneurship that accelerate discovery to true patient impact. I am the founder of and executive director of the Max Harry Weil Institute for Critical Care Research and Innovation which is the largest critical care research enterprise in the U.S. I also led the design and implementation of Michigan Medicine's Fast Forward Medical Innovation program and served as its inaugural Executive Director from 2013-2018. I am a serial innovator and entrepreneur in the field of emergency and critical care medicine and the recipient of Innovation and Commercialization awards from Virginia Commonwealth University, the University of Michigan Medical School, and the Department of Defense. I am a named inventor on numerous patents and have founded over 8 companies. Five of my inventions have resulted in FDA approved products.

In collaboration with the U.S. Army and its Joint Special Operations Training Medical Center, I developed and medically directed special training programs, which have been responsible for providing clinical training to over 1000 Special Operation Combat Medics. For this work, the



Case: 24-1285



Document: 25-3

North Campus Research Complex 2800 Plymouth Road Ann Arbor, MI, 48109 (734) 647-4751

Filed: 01/10/2024

Department of the Army and the Joint Special Operations Training Center awarded me a Certificate for Patriotic Civilian Service. I am also a Lieutenant Colonel in the U.S. Army Medical Corps and its 948th Forward Resuscitation Surgical Team deploying to Afghanistan in support of Operation Freedom's Sentinel and the 10th Special Forces Group (Airborne).

Page: 277

I have published over 200 peer-reviewed articles and book chapters. I am the recipient of the Society of Academic Emergency Medicine's Excellence in Research Award as well as the American College of Emergency Physicians Outstanding Contributions in Research Award. I serve on numerous editorial and review boards in the field of resuscitation, emergency and critical care medicine, and also serve on the executive committee for the Trauma Hemostasis and Oxygenation Research (THOR).

Transformative lifesaving technologies do not get to a patient's bedside by themselves. The process requires a deep understanding of physiology, intellectual property, regulatory challenges, the market, as well as numerous other areas. This work costs significant amounts of resources, including time and money. The way innovators are able to protect such investments and hopefully recoup the investment is through intellectual property rights. Without enforcing such rights, the investments in companies developing life altering technologies will lose all incentive, and the public health will be the victim. For that reason alone, I support the exclusion rights as being in the public interest.

I am also very concerned about the proliferation of "medical devices" like the Apple Watch with pulse oximetry. These are not "medical devices" as the FDA would use the term. Indeed, I understand only software associated with the ECG feature of certain Apple Watches is FDA cleared. Apple has not received FDA clearance for its pulse oximeter and based on data collected by Masimo, it is certainly not clear Apple would receive FDA clearance for its pulse oximeter. Despite this, it is my belief that confusion abounds in that many patients and medical professionals believe or at least use devices such as the Apple Watch as if they are FDA approved.

Specifically, Masimo's White Paper comparing the Masimo W1 to the Series 7 Watch with pulse oximeter obtained an adjusted  $A_{RMS}$  that would not meet current FDA clearance requirements. The results show the Series 7's pulse oximeter should not be used by medical professionals or patients, particularly because continuous measurements of blood oxygen saturation in patients is typically required.

I have serious concerns regarding patients treating an Apple Watch pulse oximeter as a medical device when such use has not been cleared by the FDA. Patients typically rely on large household brand-name technical companies like Apple to provide products that are beneficial, and not simply contain novelty functionalities. Apple's advertising of these medical functionalities appears to be an attempt to mislead the public into purchasing the devices as if it were a medical

<sup>1</sup> https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A\_Whitepaper\_Masimo\_W1\_US\_v4.pdf?v=1670952306 ("White Paper")





North Campus Research Complex 2800 Plymouth Road Ann Arbor, MI, 48109 (734) 647-4751

aid. I was shocked to see a video for the Apple Watch with pulse oximetry (referred to blood oxygen saturation) as something important to patients in view of the COVID-19 pandemic.<sup>2</sup> Although using blood oxygen saturation is useful for a physician, that does not mean the Apple Watch is capable of providing meaningful data—in my view it is not the type of device patients or physicians should rely upon for any medical purpose.

Moreover, contrary to the representations made by Apple in its marketing, the Apple Watch is not something that patients worried about COVID-19 should be relying on especially when there are FDA approved alternatives available. The Apple watch does not provide continuous measurements, much less claim to have medical grade capabilities in the pulse oximetry feature. Thus, I believe Apple's insinuation in the video that its watch is capable of providing "an indication of how well [your cardiovascular system] is functioning and of your overall respiratory and cardiac health" endangers public health. These current parameters provided and advertised by Apple simply do not have the fidelity and accuracy required for medical decision making.

In summary, I believe Apple's pulse oximetry, combined with its sale and marketing of that feature, has potential to harm the public health. Apple should not be allowed to use the inventions of other innovators based on unsupported allegations that its products might help people achieve improved outcomes. The public's interest in strong intellectual property rights, which will dictate future investments in future live-saving technologies, far outweighs the public's need for these novelty devices.

Very Respectfully,

Hair R. Want

Kevin R. Ward, MD, FACEP, FAAEM

Executive Director: Max Harry Weil Institute for Critical Care Research and Innovation

Professor Departments of Emergency Medicine and Biomedical Engineering

University of Michigan Medicine

LTC U.S. Army MC

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<sup>&</sup>lt;sup>2</sup> https://www.youtube.com/watch?v=YKQFaPRObp8 at 2:42-3:28.

# **EXHIBIT 25**

## UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON, D.C.

In the Matter of

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

PUBLIC INTEREST STATEMENT OF NON-PARTY PETER PRONOVOST, MD

My name is Peter J. Pronovost, M.D., Ph.D., F.C.C.M, and I am the Chief Quality & Clinical Transformation Office at University Hospitals. I am a patient safety champion, innovator, critical care physician, a researcher (publishing over 800 peer reviewed publication), entrepreneur (founding a health care start-up that was later acquired) and a global thought leader on health policy. My scientific work leveraging checklists to reduce catheter-related bloodstream infections has been shown to have saved thousands of lives. Time Magazine has named me one of the 100 most influential people in the world and in 2008. I received the MacArthur Foundation's Fellowship often referred to as a "genius grant." I chronicled my work helping improve patient safety in my book, *Safe Patients, Smart Hospitals: How One Doctor's Checklist Can Help Us Change Health Care from the Inside Out*.

Founded in 1886, University Hospitals serves the needs of patients through an integrated network of 21 hospitals (including five joint ventures), more than 50 health centers and outpatient facilities, and over 200 physician offices in 16 counties throughout northern Ohio. As Chief Quality & Clinical Transformation Officer, I am charged with fostering ideation and implementation for new protocols to eliminate defects in value and thereby enhance quality of care; developing new frameworks for population health management for UH's more than one million patients; and managing the UH Accountable Care Organization (ACO) Network – one of the nation's largest – comprising more than 581,000 members. In this role, I champion a new focus of keeping people "Healthy at Home." I am also a professor of anesthesiology and critical care medicine, surgery, nursing, and health policy and management at the Johns Hopkins University School of Medicine.

Previously, I served as the Senior Vice President for Patient Safety and Quality at Johns Hopkins Medicine as well as the founder and director of the Johns Hopkins Medicine Armstrong

Institute for Patient Safety and Quality. In this role, I worked to eliminate all harms in one health system following on success in eliminating one harm in most health systems across the U.S. I also served as the Senior Vice President for Clinical Strategy and the Chief Medical officer for UnitedHealthcare. I was elected to the National Academy of Medicine in 2011, elected as Fellow of the American Academy of Nursing and has received multiple honorary degrees. I am an advisor to the World Health Organizations' World Alliance for Patient Safety and regularly address U.S. Congress on patient safety. In response to a White House executive order, I co-chaired the Healthcare Quality Summit to modernize the Department of Health and Human Services quality measurement system.

I write to in response to the Commission's solicitation of comments on public interest issues raised by the ALJ's recommendations for relief in Investigation No. 337-TA-1276. In my view, the recommended relief serves the public interest given the strong public interest in incentivizing investment into medical innovations, which protect life-changing and life-saving technologies. Since the Pandemic, patients are using home monitoring devices as diagnostic tests and assume that devices on the market are accurate to make those diagnoses. Yet the accuracy of these home devices varies widely especially among non-medical grade devices. The continued use by patients of non-medical-grade devices such as the Apple Watch pulse oximetry puts those patients at risk for misdiagnosis and harm. The patients assume that these devices provide accurate diagnosis, and unfortunately that assumption is largely inaccurate with non-medical grade devices. Misdiagnosis is one of the major causes of preventable harm and FDA can reduce this harm by ensuring that devices used for home diagnoses are medical grade. The public interest statements from those claiming to rely on those measurements for their medical care did not provide studies supporting such use, and I am not aware of such studies.

The Apple Watch takes measurements on demand, but the user's hand must be in a particular position and remain motionless. The devices can also take intermittent measurements, provided that same motionless specific position is met. The Apple Watch does not provide continuous measurements. The lack of effectiveness of the Apple Watch is illustrated by Masimo's White Paper, which compares the Masimo W1 to the Apple Watch Series 7 oximeter. <sup>1</sup>

Table 7 of the White Paper illustrates how the Apple Watch is insufficient for patients, catching less than 7% of the dangerous desaturation events, comparted to the Masimo W1 catching 100% of such events. By detecting such a low percentages of desaturations, the Apple Watch is simply not reliable enough to be useful.

Table 7. Tabulated Summary of Fast Desaturation Events and Detection Rates for Masimo W1 vs Apple Watch

Test Configuration	Number of Subjects	Number of Valid Events	Detection Rate for Masimo W1	Detection Rate for Apple Watch
Configuration 1	7	49	49/49=100%	3/49=6.1%
Configuration 2	8	60	60/60=100%	4/60=6.7%

Detection Rate =  $(Nt / Ndesat) \times 100 (\%)$ , Nt = Number of Detected Event by Test Device, Ndesat = Number of All Valid Fast Desaturation Events by Reference SpO2

Masimo's White Paper also casts serious doubts on the measurements obtained by the Apple Watch Series 7. Although the Masimo W1 tracks measurements taken via blood draws closely, the Apple Watch—even when it gets a reading— is not at clinical-grade accuracy.

<sup>&</sup>lt;sup>1</sup> https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A\_Whitepaper\_Masimo\_W1\_US\_v4.pdf?v=1670952306 ("White Paper")

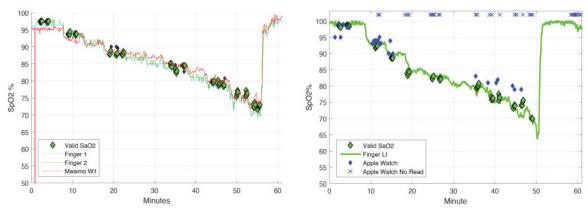


Figure 5.

Representative saturation vs time plots from subjects monitored with Masimo W1 (left panel) and Apple Watch (right panel) during blood desaturation studies. Masimo W1 SpO2 values are recorded as red line. The Apple Watch SpO2 values are shown as blue diamonds when values could be obtained. When no value could register, an "X" is shown at the top. The valid reference arterial blood saturation (SaO2) value is shown in green diamonds for each device. There are two additional SpO2 references (from Masimo RD SET\* Sensors) shown for the Masimo W1 study (Fingers 1 and 2) and one additional SpO2 reference for the Apple Watch (Finger L1). The Masimo W1 tracked with the reference pulse oximeters and SaO2 values quite well. However, there are numerous examples of "failure to read" (X) for the Apple Watch.

The calculated  $A_{RMS}$  for the Apple Watch indicates that the device could not be cleared by the FDA and is unlikely to actually assist patients

Table 6. Tabulated Summary of Performance Statistics for Masimo W1 and Apple Watch

		Bias (%)	Precision (%)	A <sub>RMS</sub> (%)	Adjusted Precision (%)	Adjusted A <sub>RMS</sub> (%)
	Masimo W1	0.2	1.5	1.5	1.6	1.6
	Apple Watch	3.1	3.2	4.4	3.4	4.6

Despite physicians touting the devices ability to calculate blood oxygen saturation, Apple states in its marketing material "Blood oxygen app measurements are not intended for medical use, including self-diagnosis or consultation with a doctor, and are only designed for general fitness and wellness purposes." I have concerns that patients will not understand this distinction and, as reflected in other public interest statements, are relying on the Apple watch to diagnose hypoxemia and monitor trends and response to treatments. No doubt, consumers love Apple

<sup>&</sup>lt;sup>2</sup> https://support.apple.com/en-us/HT211027

products; but this increases the risk that consumers will use the watch for medical purposes. This

could result in in false negatives, underdiagnosed hypoxemia and false positives where people may

unnecessarily seek healthcare and cause psychological distress. Indeed, the Journal of the

American Medical Informatics Association published a study concluding false positives from the

Apple Watch "may lead to overutilization of healthcare resources."<sup>3</sup>

Additionally, as someone who started a small-company, I understand the importance of

strong intellectual property rights to innovation. Masimo is an innovation leader, and its products

have been proven to have clinical benefit. It serves the public interest to provide incentives for the

innovators to bring the next life-saving devices to market. Accordingly, the enforcement of

Masimo's intellectual property rights will help foster future investment and innovations in

healthcare. This will have a real impact on patient healthcare.

In sum, the Apple watch pulse oximeter is not medical grade, yet people claim to be using

it as a medical device, potentially causing harm. I support the recommended remedial orders and

believe they are in the public interest. I encourage the Commission to block the importation of

Apple Watches that include the pulse oximetry sensor. To the extent other consumers desire the

other features, Apple has the watches like the Apple Watch SE readily available. I also encourage

the FDA to require that pulse oximeters be medical grade as we have no way to ensure consumers

will not use them for medical purpose, and when they do, it can cause them harm.

Respectfully submitted,

Dated: February 26, 2023

/s/ Peter Pronovost

Peter Pronovost, MD

<sup>3</sup> https://academic.oup.com/jamia/article/27/9/1359/5911974?login=false

5

MAS-ADD-361

# **EXHIBIT 26**

## UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON, D.C.

In the Matter of

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

PUBLIC INTEREST STATEMENT OF NON-PARTY PATIENT SAFETY MOVEMENT FOUNDATION

My name is Michael A.E. Ramsay, MD, FRCA, and I am the Chief Executive Officer of the Patient Safety Movement Foundation ("PSMF"). I have served on the board of PSMF since 2013. I am also Chairman Emeritus of the Department of Anesthesiology and Pain Management at Baylor University Medical Center in Dallas, Texas, and I serve as a member of the Baylor University Medical Center Board of Trustees.

As the Past Director of Anesthesia for the liver transplant program at Baylor, I have personally provided anesthesia for over 1,000 transplant recipients. As part of my prior practice, I first learned about Masimo's life-changing technologies. I was privileged to meet Masimo's founder, Joe Kiani, soon after he founded Masimo. I was impressed with his tremendous drive to create technology that will make our healthcare systems safer. In 2014, Joe continued these efforts by creating the Patient Safety Movement Foundation, a non-profit aimed at reducing the 200,000 preventable deaths in U.S. hospitals each year to zero. I now lead that organization. We aim to achieve zero preventable patient harm and death across the globe by 2030.

On behalf of PSMF, I write in support of the recommended orders in the Commission's investigation regarding Apple's unfair importation of watches containing pulse-oximetry functionality. PSMF believes that devices like the Apple Watch, which do not offer hospital-grade pulse oximetry functionality, are potentially dangerous to the public, particularly given Apple's historic marketing of the feature. Consumers will believe based on this advertising that the Apple Watch will provide them with accurate and clinically relevant information. This is especially true given Apple's public perception as a technology giant. If Apple says the device measures blood oxygen saturation, most consumers will not question that.

The Apple Watch Series 6 was launched in Fall of 2020 in the midst of the COVID-19 pandemic. Reports suggested starting in 2020 that COVID-19 had a fairly significant effect on the

body's ability to oxygenate blood.<sup>1</sup> This led to sales of fingertip pulse oximeters increasing 500% during a single week in February 2020 and by mid-May the devices were sold out in many stores. *Id.* 

Apple's launch of the Series 6 capitalized on this market demand even thought it was not clinically validated.<sup>2</sup> Apple's launch video featured Dr. Sumbul Ahmad Desai, MD, the VP of Health at Apple. In the video she was asked to talk "about blood oxygen and its importance to your health." *Id.* at 2:36-2:42. She stated:

Blood oxygen saturation also known as SpO<sub>2</sub> is like a vital sign. It's a key measurement that contains critical information about your breathing and circulation. Apple Watch is already a powerful health tool with apps that measure heart rate and hear rhythm and now adding blood oxygen brings another valuable health measurement to users. Blood oxygen and pulse oximetry are terms that we've heard a lot about during the COVID pandemic. As you breathe your heart and lungs work together to deliver oxygen throughout your body. Blood oxygen saturation is an indication of how well this system is functioning and of your overall respiratory and cardiac health and pulse oximetry is how you measure it.

*Id.* at 2:42-3:28

Apple's touting of the device during the COVID pandemic, despite the lack of validation as providing clinically meaningful data to patients, posed a risk to any individual who sought to use the device as a way of protecting themselves from the adverse consequences of COVID. The risk is highlighted by Masimo's recent White Paper related to its Masimo W1 healthwatch that contains a study comparing the Masimo W1 to the pulse oximeter in the Apple Watch Series 7.<sup>3</sup>

As shown in Table 6 of the White Paper—reproduced below, the Adjusted ARMS for the

https://www.washingtonpost.com/lifestyle/wellness/pulse-oximeter-covid-19-coronavirus/2020/05/18/5b6f8a98-96df-11ea-9f5e-56d8239bf9ad story.html

https://www.youtube.com/watch?v=YKQFaPRObp8

<sup>3 &</sup>lt;u>https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A\_Whitepaper\_Masimo\_W1\_US\_v4.pdf?v=1670952306</u>

Apple Watch was below that required for FDA clearance, while the Masimo W1 achieved results at a hospital-grade level.

Table 6. Tabulated Summary of Performance Statistics for Masimo W1 and Apple Watch

	Bias (%)	Precision (%)	A <sub>RMS</sub> (%)	Adjusted Precision (%)	Adjusted A <sub>RMS</sub> (%)
Masimo W1	0.2	1.5	1.5	1.6	1.6
Apple Watch	3.1	3.2	4.4	3.4	4.6

Moreover, unlike the Apple Watches with pulse-oximetry functionality, the Masimo W1 offers continuous monitoring of SpO<sub>2</sub>. This is incredibly important. Rapid blood-oxygen desaturations are a serious problem and often occur when someone is sleeping. For example, it can occur because of sleep apnea. Masimo's study indicates the Masimo W1 successfully "catches" these dips in oxygen saturation, while the Series 7 barely functions due to its non-continuous monitoring and its need to be positioned perfectly. This is shown in Table 7 of the White Paper reproduced below:

Table 7. Tabulated Summary of Fast Desaturation Events and Detection Rates for Masimo W1 vs Apple Watch

Test Configuration	Number of Subjects	Number of Valid Events	Detection Rate for Masimo W1	Detection Rate for Apple Watch
Configuration 1	7	49	49/49=100%	3/49=6.1%
Configuration 2	8	60	60/60=100%	4/60=6.7%

Detection Rate = (Nt / Ndesat)  $\times$  100 (%), Nt = Number of Detected Event by Test Device, Ndesat = Number of All Valid Fast Desaturation Events by Reference SpO2

In my opinion, this data indicates that the blood oxygen sensor in the Apple Watch does nothing beneficial for the public welfare.

It is also not clear that any of the other features of the Apple Watch offer a net benefit to the public health. Although I have read anecdotal reports of people with Apple Watches believing it led to them getting checked out for a heart issue or it contacted authorities after a crash, it isnot clear whether these beneficial incidents are merely random or that they justify the significant false

positives. To the extent the watch is alerting authorities when there is no danger or sending users to emergency rooms when they are perfectly healthy, there is a huge societal cost.

It is my understanding that the Apple Watch has been criticized for these false positives with respect to numerous of its apps. For example, a recent article in the New York Times criticized the crash detection features and indicated it was creating a heavy burden on 911 operators in certain parts of the country.<sup>4</sup> The Journal of the American Medical Informatics Association, also published a study concluding that false positives from the Apple Watch "may lead to overutilization of healthcare resources." The study concluded "The Food and Drug Administration and Apple should consider the unintended consequences of widespread screening for asymptomatic ("silent") atrial fibrillation and use of the Apple Watch abnormal pulse detection functionality by populations in whom the device has not been adequately studied." *Id*.

The cost of a "false positive," is difficult to calculate. A single errant 911 call might only cost a small amount of an operator's time. But, it could also lead to first responders being unavailable to provide life-saving treatment to an actual crash victim. There is also the emotional toll of a patient believing they have a serious heart condition, only to find out it was false.

A broken clock might be right twice a day, but when caring for patients you need a clock that works. That is what PSMF seeks to achieve in healthcare, and that is what Masimo's innovations have helped the healthcare industry move to. I fear that investment in these life-saving technologies might cease if companies like Apple are allowed to infringe the intellectual property rights of innovative companies like Masimo without consequence. It is in the public interest to protect these creators and accordingly, an exclusion order will benefit the public welfare and

4

https://www.nytimes.com/2023/02/03/health/apple-watch-911-emergency-call.html

https://academic.oup.com/jamia/article/27/9/1359/5911974?login=false

further PSMF's goals to rid the world of preventable medical errors.

Best regards,

Michael Ramsay, MD

# EXHIBIT 27

# UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON, D.C.

In the Matter of

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

PUBLIC INTEREST STATEMENT OF NON-PARTY MEDICAL DEVICE MANUFACTURERS ASSOCIATION (MDMA)

Non-party the Medical Device Manufacturers Association (MDMA) responds to the Commission's solicitation of comments on public interest issues in Investigation No. 337-TA-1276. The recommended relief is in the public interest given the need to protect the patent rights of medical device innovators from the threat of large companies who can afford to engage in "efficient infringement" as a business strategy.

#### The Medical Device Manufacturers Association Supports Enforcement of IP Rights

MDMA is a national trade association in Washington, DC providing educational and advocacy assistance to innovative and entrepreneurial medical technology companies. MDMA's mission is to promote public health and improve patient care through the advocacy of innovative, research-driven medical technology. Since 1992, MDMA has been the voice for medical innovation, proactively helping to shape policies that impact the innovators. To achieve its goals, MDMA represents its members' collective interests before the United States Congress, the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and other federal agencies that develop or implement policies that affect the medical device industry. MDMA is particularly concerned about continued erosion of intellectual property rights of its members, who must protect their innovations to ensure that medical technology flourishes.

#### **Apple's Lack of Respect for Innovation**

Over several years, Apple has executed a strategy to position its consumer products not only within the health and wellness space, but also within the healthcare field. This includes an emphasis on healthcare applications of Apple products.<sup>1</sup> In its push to extend the reach of its consumer products, Apple has disregarded the patent rights of innovators. Apple founder Steve Jobs welcomed the practice of taking others' ideas. In Jobs' view, "[i]t's better to be a pirate than join the navy," and he embraced Picasso's adage, "good artists copy, great artists steal." Jobs emphasized that Apple has "always been shameless about stealing great ideas."

<sup>&</sup>lt;sup>1</sup> https://www.apple.com/healthcare/ (claiming "Our technology helps [healthcare providers] work effectively within hospitals, connect remotely with patients, and conduct groundbreaking medical research").

<sup>&</sup>lt;sup>2</sup> https://qz.com/1719898/steve-jobs-speech-that-made-silicon-valley-obsessed-with-pirates/.

<sup>&</sup>lt;sup>3</sup> https://thenextweb.com/news/steve-jobs-shameless-stealing-great-ideas.

#### **Apple's Practice of "Sherlocking" Innovations from Third Parties**

In 2011, Apple created a section in its AppStore referred to as "Apps for Healthcare Professionals," which it later divided into subcategories such as reference, medical education, EMR and patient monitoring, nursing, imaging, patient education, and personal care.<sup>4</sup> In 2014, Apple released its own "HealthApp" and a developer platform called HealthKit to allow developers to make health apps that integrate with Apple's app.<sup>5</sup> Unfortunately, Apple has developed a reputation for mining internal data from these apps to exploit the ideas of its developers.<sup>6</sup> The experience of having an app or feature become obsolete because Apple has copied it is referred to as "Getting Sherlocked."

#### **Apple's Targets Include Medical Device Innovators**

One target of Apple's piracy are medical device innovators such as Masimo, the Complainant in this Investigation which has grown from a startup to the leading supplier of hospital pulse oximetry in the world. Masimo alleges that Apple approached it years ago, seeking to incorporate Masimo's technology into Apple products. But instead, Apple opted to recruit Masimo engineers and executives, and eventually released the infringing products. Masimo is also bringing its medical grade technologies directly to consumers. Masimo has released directly to consumers a pulse oximeter worn on the user's wrist that *continuously* measures a user's oxygen saturation, known as the Masimo W1. A recent article comparing the Masimo W1 to the Apple Watch explains that the "Masimo W1 feels like a tool" contrasting that to the Apple watch as more like a "toy." <sup>7</sup> It explains that the W1 is better for continuous monitoring for health reasons. *Id*.

Masimo previously introduced wrist-worn, continuous, wireless, hospital pulse oximetry technology for home use during COVID-19, with Masimo SafetyNet. This product provided hospital grade

<sup>&</sup>lt;sup>4</sup> See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4029126/

 $<sup>^{5} \ \</sup>underline{\text{https://www.cnbc.com/2016/05/24/tim-cook-why-the-apple-watch-is-key-in-the-enormous-health-care-market.html}$ 

<sup>&</sup>lt;sup>6</sup> Reed Albergotti, "How Apple uses its App Store to copy the best ideas," *The Washington Post*, September 5, 2019, *available at* <a href="https://www.washingtonpost.com/technology/2019/09/05/how-apple-uses-its-app-store-copy-best-ideas/">https://www.washingtonpost.com/technology/2019/09/05/how-apple-uses-its-app-store-copy-best-ideas/</a>

<sup>&</sup>lt;sup>7</sup> https://www.verywellhealth.com/health-tracking-watches-masimo-vs-apple-7111935

pulse oximeters for the home. The data is transmitted to the hospitals, allowing them to monitor patients from their homes. This was the only such product, and it received substantial news coverage for its innovative approach to solving the hospital overcrowding issue.<sup>8</sup>

Apple's expressing interest in a company's medical device technology, only to then enter the market using such technology without permission, was also the subject of another Investigation of Apple — in 337-TA-1266, which also resulted in a finding of a Section 337 Violation by Apple. The infringement was by the Apple Watch that has been found to infringe Masimo's patents, but the infringing medical technology is different. The use of Masimo's technology heightens this theft, because unlike AliveCor, Masimo is the leading pulse oximetry supplier to hospitals worldwide. Its technology has proven to offer clinical benefits above other pulse oximeters<sup>9</sup> and to improve clinical outcomes.<sup>10</sup>

Apple's conduct as alleged by Masimo, AliveCor and others indicates a pattern of "efficient infringement"—which has been described as "the use of another company's patents without authorization on the understanding that litigation will be too slow to meaningfully stop the infringement and will ultimately only result in the payment of a royalty if the suit is lost."

Apple's former patent counsel stated that such a practice could be viewed as a "fiduciary responsibility" for "cash-rich firms that can afford to litigate without end." Apple has claimed to repudiate these comments, but its conduct suggests an Efficient Infringement strategy to quickly get new products and features on the market to curb competition.

<sup>8</sup>https://www.youtube.com/watch?v=pDozdvvbCMA;https://www.youtube.com/watch?v=2SskwKPn\_u4; https://www.youtube.com/watch?v=I7ul1vGWcQM;https://www.youtube.com/watch?v=Ivl0FJy32vs
9 https://www.masimo.com/evidence/pulse-oximetry/set/

<sup>&</sup>lt;sup>10</sup> https://onlinelibrary.wiley.com/doi/full/10.1111/j.1651-2227.2010.02001.x; de-Wahl Granelli A et al. *BMJ*. 2009;Jan 8;338., and Zhao et al. *Lancet*. 2014 Aug 30;384(9945):747-54; McGrath S, et al J Patient Safety. 2021; 17(8):557-561;

<sup>11 &</sup>lt;u>https://docs.house.gov/meetings/JU/JU05/20200729/110883/HHRG-116-JU05-20200729-OFR059.pdf</u>

<sup>&</sup>lt;sup>12</sup> *Id.*; *see also* <a href="https://cpip.gmu.edu/2016/10/12/supreme-court-should-not-reward-efficient-infringement-in-apple-v-samsung/">https://cpip.gmu.edu/2016/10/12/supreme-court-should-not-reward-efficient-infringement-in-apple-v-samsung/</a>; <a href="https://ipwatchdog.com/2019/03/19/apple-pays-patent-infringement-important-legal-cases-continue/id=107425/">https://ipwatchdog.com/2019/03/19/apple-pays-patent-infringement-important-legal-cases-continue/id=107425/</a>

This strategy ignores that "the public interest favors the protection of intellectual property." Certain Digital Television Products and Certain Products Containing Same and Methods of Using Same, Inv. No. 337-TA-617, Comm'n Op., at 9 (Aug. 21, 2009) ("Digital TV Products") (internal quotation marks and citation omitted). The ITC should deny relief only where "the statutory public interest concerns are so great as to trump the public interest in enforcement of intellectual property rights." Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chips, Power Control Chips, and Products Containing Same, Including Cellular Telephone Handsets, Inv. No. 337-TA-543, Comm'n Op., at 153-154 (June 19, 2007). The Commission "need only decide that the public interest does not preclude" the remedy. Certain Cigarettes and Packaging Thereof, Inv. No. 337-TA-643, 2009 ITC LEXIS 2464, Comm'n Op., at \*46 (Oct. 1, 2009).

Any argument by Apple that the remedial orders should be avoided due to widespread use of its infringing Apple Watch should be rejected. That would be tantamount to arguing if you can infringe in a huge way, then you should escape the consequences. Such a policy encourages infringement. Enforcement should also not depend on the size of the company subject to the remedial orders. Apple's assertion that it has many customers for its infringing Watches does not justify Apple's infringement or provide an excuse.

MDMA believes that protecting intellectual property rights is particularly important in medical technology, where innovation has saved countless lives and improved the quality of life for countless others. The investment required to bring innovative technologies to market is enormous, involving not only a commitment to product development but also to clinical research, which is necessary to validate the safety and efficacy of medical technology. Masimo has made these investments and healthcare has improved as a result. Allowing the theft of technology from pioneering companies seriously undermines the ability of companies to raise the funds necessary to innovate and continue to improve healthcare for Americans.

#### There are Alternative Options to the Infringing Pulse Oximetry Feature

Apple has heavily marketed pulse oximetry on the Apple Watch, but numerous other wrist-worn devices that also provide non-medical pulse oximetry are available on the market from companies such as

Fitbit, Samsung, Garmin, Amazon and others.<sup>13</sup> In addition, Masimo offers the W1, which offers clinical

grade continuous pulse oximetry. We understand that this same Masimo W1 is sold to hospitals outside the

United States. Philips, the world leader in multi- parameter, critical care patient monitors, recently

announced it will add compatibility to the Masimo W1 for telehealth.<sup>14</sup> The Apple Watch, on the other

hand, provides sporadic measurements, only under perfect conditions.

Apple Can Remove the Infringing Features Without Consumer Impact

Apple also already sells the Apple Watch SE, which offers the smartwatch features of the Apple

Watch at issue in this Investigation, without the infringing pulse oximetry. And Apple releases a new

version of the Apple Watch every year and certainly has resources to remove infringing features while

including other features not at issue.

The Recommended Remedies Support American Innovation

MDMA believes providing companies with appropriate relief at the ITC is essential to protect

American innovation and encourage innovative companies to pursue real medical solutions. An exclusion

order and cease-and- desist order preventing Apple from importing and distributing products that rely on

Masimo's innovation are the appropriate remedies. A conclusion otherwise would encourage "efficient

infringement" by Apple and others and would disincentivize innovation. This will have a dramatic impact

on smaller companies who do not have the resources to compete unless they can protect their innovations.

Sincerely,

Dated: February 27, 2023

Mark Leahey President & CEO

Not to Lech

Medical Device Manufacturers Association (MDMA)

<sup>13</sup> https://www.androidcentral.com/best-smartwatches-can-measure-blood-oxygen-saturation-levels

https://www.masimo.com/company/news/news-media/#2c48b39a-5aba-4950-8096-

305881a036f2

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MAS-ADD-375

# **EXHIBIT 28**



## Masimo W1™

Hospital-Grade Continuous Monitoring of SpO2 and Other Parameters in a Consumer Watch



WHITEPAPER

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#### I. INTRODUCTION

Continuous pulse oximetry has been widely used and recognized for over four decades as an essential clinical monitoring tool for detecting physiological changes in the cardio-pulmonary system. For years, positive outcome studies did not exist; however, no anesthesiologist would take their patient to the operating room without one. Masimo SET® has also been shown to help clinicians reduce severe retinopathy of prematurity in neonates, improve CCHD screening in newborns, and, when used for continuous monitoring with Masimo Patient SafetyNet® in post-surgical wards, reduce rapid response team activations, ICU transfers, and costs.

Masimo SET® is now widely recognized as the industry leader in in pulse oximetry. Masimo SET® is used to monitor more than 200 million patients annually; and, is the primary pulse oximetry technology used at nine of the top 10 hospitals as ranked in 2022-23 *U.S. News & World Report* Best Hospitals Honor Roll. Masimo SET® has been shown in over 100 peer-reviewed studies to outperform other pulse oximeter technologies in hospital use. As the world leader in hospital-grade pulse oximetry technology, Masimo has developed the first consumer health watch, Masimo W1™, to offer the accuracy and reliability of advanced hospital-grade continuous pulse oximetry in a convenient, wrist-worn wearable device. For Masimo W1, we adapted monitoring technology based on Masimo SET® pulse oximetry to optimize the capture of health data on the wrist.

This whitepaper reviews basic features of the Masimo W1 watch, emphasizing the tangible benefits of hospital-grade technology and the importance of continuous accurate real-time health data. Next, several common and important confounders of SpO2 measurement are reviewed (e.g. motion, low perfusion, and skin pigmentation), along with the solutions already addressed by Masimo Signal Extraction Technology® (SET®) that are incorporated into the Masimo W1 watch. The next section surveys the head-to-head comparison of the Masimo W1 watch versus the Apple Watch in terms of accuracy, as well as ability to detect falling SpO2 values during sleep and during spot check with wrist and watch held in the sideways position. The penultimate section introduces a brand new parameter Hydration Index (Hi), a feature only available by Masimo, and is of importance for healthy athletes. Finally, the "Eye to the Future" section provides a glimpse of upcoming features that will be available in yet to be released Masimo wrist-wearable products. This white paper anticipates the potential clinical benefits of the Masimo W1 after its FDA 510(k) clearance, which is currently pending at the time of this publication (Dec. 13, 2022).

#### II. THE MASIMO W1 HEALTH WATCH SOLUTION

Masimo has used its innovation and expertise in signal processing, photonics, bio-sensor design, to integrate its advanced continuous pulse oximetry technology into the Masimo W1 health watch (Figure 1).



Figure 1. Masimo W1 Advanced Health Tracking Watch



The Masimo W1 watch offers continuous health parameter data, including hospital-grade blood oxygen saturation (SpO2), pulse rate, pulse rate variability, heart rate, respiratory rate, perfusion index (Pi), pleth variability index (PVi), calorie count, and a noninvasive continuous measurement of hydration, hydration index (Hi) (Figure 2). As part of a future update, Masimo W1 will also measure temperature and VO2Max and provide continuous health data tracking and oversight. The Masimo W1 can be used for a wide variety of applications in diverse settings and can help healthy individuals better understand and track their overall health, fitness, and daily activities. The Masimo W1 watch is currently limited to health and wellness applications, as 510(k) medical device clearance is pending.

#### Oxygen level (SpO<sub>2</sub>)\*



A continuous measurement of functional oxygen saturation of arterial hemoglobin. Essentially, the blood oxygen levels, which can change with heart and lung function, activity, and altitude.



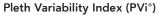
#### Pulse rate (PR)

A continuous measurement of the heart rate (beats per minute) derived from the pleth waveform. PR changes with activity and stress.



#### Pulse Rate Variability (PRV)

A continuous measurement of the variation in time between each pulse. The PRV changes with exercise and stress.





A dynamic index between 0-100 based on changes in perfusion index. PVi is affected by fluid volume changes occurring during the respiration cycle and typically increases with lower intravascular fluid levels.



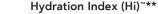
#### Perfusion Index (Pi)

A continuous calculation of the relative strength of the pulse, which changes based on circulation.





On-demand



A dynamic index between -5 to +5 which measures the relative intra-cellular fluid (water) loss and gain based on changes in tissue water content. Hydration optimization can improve physical exercise endurance, sleep quality, cognition, mood, and more.



#### Heart rate (HR)

The number of times the heart beats in a minute, based on electrical signals from the ECG waveform.



#### Respiration Rate (RRp®‡)

A continuous measurement of respiration rate (breaths per minute) derived from changes in the pleth waveform. Advanced signal processing is used to calculate RRp, which can change with physical activity, or mental or emotional states.



#### Activity (Steps)

The level of physical activity captured due to motion, represented in steps count.



#### Calories (kcal)

A calculated value of burned calories (level of energy consumption) based on the basal metabolic rate and physical exertion, represented as kcal. The calculated value also incorporates user profile data (e.g., biological sex, age, weight and height).



\* Arterial oxygen saturation. \*\* Available with the Consumer Health version of Masimo W1. ‡ RRp stands for respiratory rate from the pleth.

Figure 2. Physiological Parameters Measured Continuously (Red) and On-demand (Blue) by Masimo W1

#### III. COMMON PULSE OXIMETRY CONFOUNDERS AND MASIMO SOLUTIONS

Masimo has been a global leader in medical-grade pulse oximetry for over 30 years. Its Signal Extraction Technology® (SET®) was designed address the common confounders of conventional pulse oximetry such as motion, low perfusion, and skin pigment. **Table 1** reviews the problems and Masimo solutions.

Table 1. Pulse Oximetry Confounders and Masimo Solutions

Conventional Pulse Oximetry Confounder	Impact on Sp02 Measurement	Addressed by Masimo SET Pulse Oximeters and CO-Oximeters	Addressed by Masimo W1 Health Watch
Motion	Non-arterial and venous noise reduce accuracy	Yes	Yes
Low Perfusion	Impaired blood flow can generate signal artifacts and decrease accuracy	Yes	Yes
Skin Pigment	Static absorbers (i.e., skin pigment, tissue thickness) affect the light absorbance signal and reduce accuracy	Yes	Yes

#### Whitepaper

Masimo addressed the confounders listed in **Table 1** (above) using advanced signal processing techniques, including parallel engines and adaptive filters, to separate the arterial signal from sources of noise (including the venous signal) and significantly reduce the impact of static absorbers such as skin pigment and tissue thickness (e.g., finger, toe, or earlobe). In addition, Masimo continues to iterate regarding enhancements to sensor design. This cutting-edge SET\* technology has enabled Masimo pulse oximeter devices to measure SpO2 accurately and minimize common confounders of conventional pulse oximetry, including motion, low perfusion, and varying skin pigmentation. These advancements served as the foundation for the hospital grade SpO2 monitoring technology now available in the Masimo W1 Watch.

#### IV. PERFORMANCE OF MASIMO W1 VERSUS APPLE WATCH SERIES 7

Recent studies were conducted in the Masimo laboratory to compare the performance of the Masimo W1 health watch with the Apple Watch Series 7 in healthy adult volunteers. This investigation included an analysis of SpO2 accuracy based on arterial blood desaturation studies, using a co-oximeter for reference arterial blood oxygen saturation (SaO2) measurements. In addition, studies assessing the ability to detect SpO2 during rapid desaturation events using the Apple watch "sleep mode" with the watch in a normal upright position, and during spot check measurements with the wrist rotated externally 90 degrees (thumb facing up), were conducted as detailed below. In all cases, the Masimo W1 resulted in far superior measurement efficacy, and remains as the only commercially available wearable device capable of accurate and continuous SpO2 measurements.

#### A. Accuracy (Based on desaturation studies compared to arterial blood samples)

Healthy adult subjects were exposed to a desaturation protocol that sequentially decreased the SpO2 in a stepwise fashion, achieving stable plateau values between 100 and 70%, while recording simultaneous SaO2 readings. The target desaturation profile is shown in **Figure 3** below.

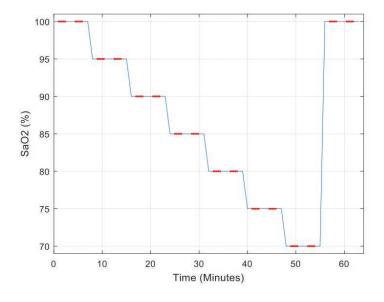


Figure 3.

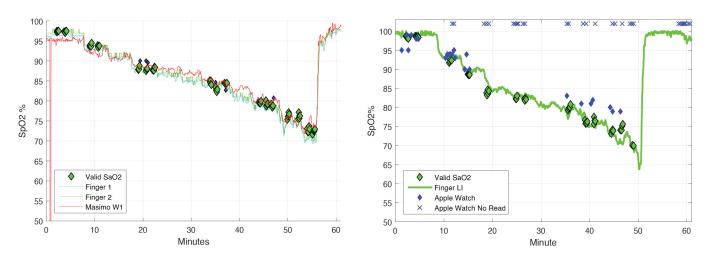
Target Blood Desaturation Profile

This figure shows the optimal oxygen saturation target levels for a desaturation study ranging from 100% sat to 70% sat. At each plateau (between red dashes), arterial blood samples are taken to match with the stable saturation value. SaO2 = arterial blood saturation

For the Masimo W1, which measures SpO2 continuously, the SpO2 measurements can be observed to synchronize with the reference SaO2 measurements. The Apple Watch measures SpO2 as a spot check reading, and spot check measurements were recorded simultaneously with the blood draw. **Figure 4** demonstrates a representative example of the data acquired by the Masimo W1 and Apple Watch during the blood desaturation protocol. The side-by-side plots derived from the Apple Watch and Masimo W1 illustrate the differences between the Masimo W1 (red line), which synchronizes with the SaO2 measurements, and the Apple Watch (blue diamond), which has spot check measurements initiated by a laboratory investigator. The failed spot check measurements with the Apple Watch (no readings) are shown with the blue X's along the top of the plots, which occurred at both high and low oxygen saturations.

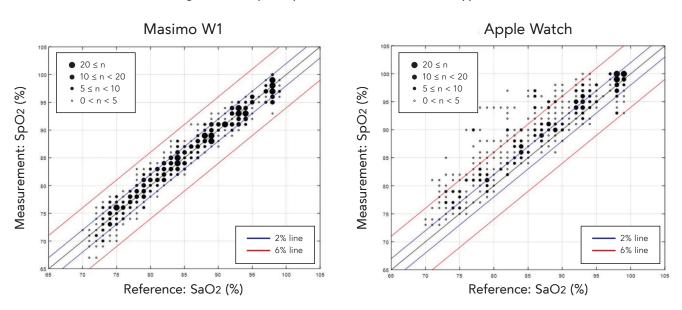
Figure 4.

Representative saturation vs time plots from subjects monitored with Masimo W1 (left panel) and Apple Watch (right panel) during blood desaturation studies. Masimo W1 SpO2 values are recorded as red line. The Apple Watch SpO2 values are shown as blue diamonds when values could be obtained. When no value could register, an "X" is shown at the top. The valid reference arterial blood saturation (SaO2) value is shown in green diamonds for each device. There are two additional SpO2 references (from Masimo RD SET\* Sensors) shown for the Masimo W1 study (Fingers 1 and 2) and one additional SpO2 reference for the Apple Watch (Finger L1). The Masimo W1 tracked with the reference pulse oximeters and SaO2 values quite well. However, there are numerous examples of "failure to read" (X) for the Apple Watch.



Summary data scatterplots of the SpO2 versus SaO2 values for the Masimo W1 (N=27) and Apple Watch (N=20) are shown in Figure 5 below.

Figure 5. Scatterplots (SpO2 vs. SaO2) of Masimo W1 and Apple Watch



#### Whitepaper

Statistical calculations for the data shown in **Figure 5** (above) included values of bias (mean SpO2-SaO2 difference), precision (standard deviation of the difference), and accuracy (root-mean-square error  $[A_{RMS}]$ ). Since the blood sampling procedure uses paired replicates nested within each subject, additional sources of variation occur that require "adjustments" of the calculated precision. Therefore, the Adjusted Precision and Adjusted  $A_{RMS}$  were calculated to account for repeated measures within subjects and within the paired replicates. The Adjusted  $A_{RMS}$  was then calculated as shown below.

$$AdjustedPrecision = \sqrt{BetweenSubjectVariance + WithinSubjectVariance}$$

$$AdjustedARMS = \sqrt{Bias^2 + AdjustedPrecision^2}$$

A summary of the performance statistics is shown in **Table 2**. Bias and adjusted precision are  $0.2\% \pm 1.6\%$  for the Masimo W1 and  $3.1\% \pm 3.4\%$  for the Apple Watch. Adjusted A<sub>RMS</sub> is 1.6% for the Masimo W1 and 4.6% for the Apple Watch. Note for all values in **Table 2**, lower numbers are better, and a typical pulse oximeter in a hospital must have and A<sub>RMS</sub> <3% for FDA clearance, and <2% to be considered a satisfactory device.

Table 2. Tabulated Summary of Performance Statistics for Masimo W1 and Apple Watch

	Bias (%)	Precision (%)	A <sub>RMS</sub> (%)	Adjusted Precision (%)	Adjusted A <sub>RMS</sub> (%)
Masimo W1	0.2	1.5	1.5	1.6	1.6
Apple Watch	3.1	3.2	4.4	3.4	4.6

Masimo W1

#### B. Detection of SpO<sub>2</sub> During Rapid Desaturations Using "Sleep Mode" and Spot Check

The fast desaturation protocol included four fast desaturation events at SpO2 plateau values between 100 and 70%. Each fast desaturation event was a three-minute-long plateau (hold) followed by two minutes of resting period. **Figure 6** illustrates the fast desaturation profile.

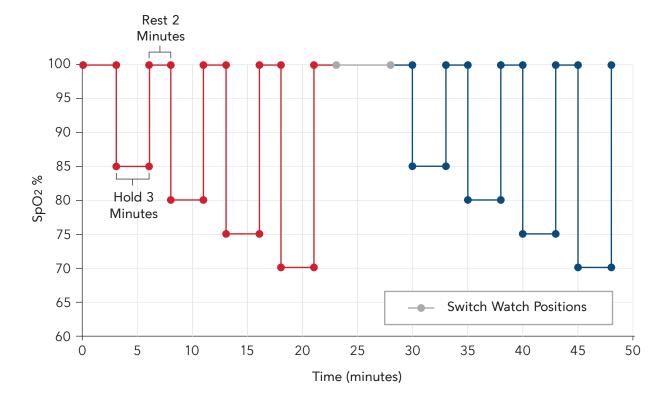


Figure 6. Fast Desaturation Profile (used for "Sleep Mode" and Spot Check)

The subjects were exposed to a fast desaturation protocol (**Figure 6** above) using two test configurations with both the Masimo W1 and Apple Watch. In both configurations, the watches were applied to the back (dorsal) side of the wrist per manufacture instructions. In Configuration 1 (used for the "sleep mode" test), both watches faced up (palm facing down). In Configuration 2 (used for the spot check testing), both watches were placed per manufacture recommendations, but the forearm was externally rotated 90 degrees from Configuration 1, so the thumb (in Configuration 2) was facing up and watch facing same direction as back (dorsum) of hand.

The Masimo Radical-7° was used to collect reference SpO2 values using disposable RD SET° sensors applied to four fingers (left Index, left ring, right index and right ring fingers) of each subject. The median SpO2 values from the four finger sensors were computed as the reference SpO2 values.

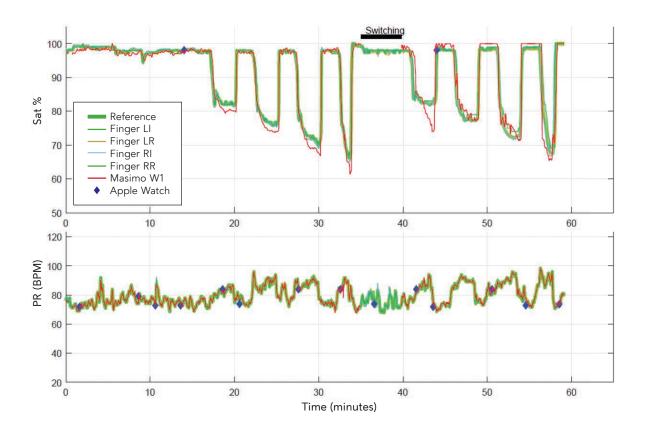
For each desaturation event, if the minimum reference SpO2 value during the event was  $\leq$  92%, it was then compared with the SpO2 readings from both watches. If the Masimo W1 also displayed a SpO2 reading  $\leq$  92%, it was recorded as a successful detection. Similarly, if the Apple Watch also displayed a SpO2 reading  $\leq$  92%, it was recorded as a successful detection.

#### B1. SpO2 Detection During Apple "Sleep Mode" (During rapid desaturations, watch facing upward)

During the "sleep mode" testing for Apple Watch, **Configuration 1** (described above) was used. The Apple Watch was set to "sleep mode" (default measurements are automatically taken approximately every 30 seconds), whereas the Masimo W1 was, by design, able to measure continuously.

Figure 7 shows a representative example of the data acquired by the Masimo W1 (red line) and the Apple Watch (blue diamond). Note that the Masimo W1 tracks with the reference device and captures every rapid desaturation event. Whereas the Apple Watch, which by default only measures approximately every 30 seconds, failed to detect any of the falling desaturation events in this subject. If the Apple watch was the only survey utilized for desaturation events, there would have been a complete failure to detect the events.

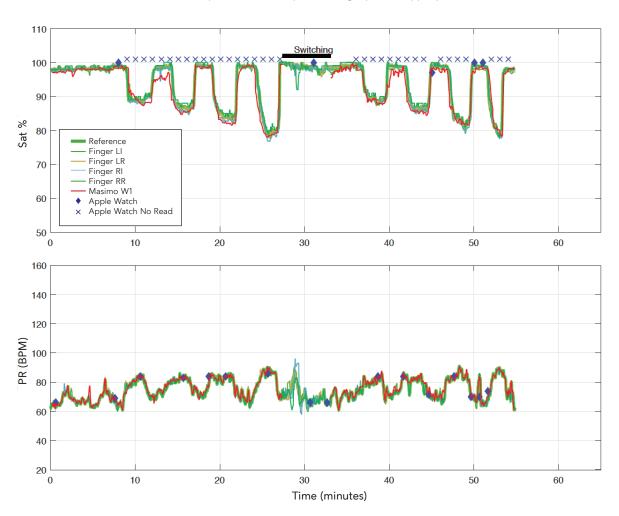
Figure 7. Representative sample from subjects monitored during rapid desaturation events with Masimo W1 (red line) vs Apple Watch in sleep mode (blue diamond) in top graph. Bottom graph depicts pulse rate tracking.



#### B2. Spot Check Detection (Read vs no-read of rapid desaturations, watch facing sideways)

The no read rate (failure rate) was determined for spot check measurements with the Apple Watch during the blood desaturation and fast desaturation studies discussed above. **Figure 8**, on the next page, shows a representative sample of the subject data acquired during fast desaturation with the Masimo W1 (red line), which measured continuously, and the Apple Watch (blue diamond) spot check measurements. Note that there were numerous episodes where the Apple Watch had no SpO2 reading (blue X), as shown in the top graph, but the pulse rate measurement occurred with fairly good fidelity (bottom graph) with both the Masimo W1 and the Apple Watch.

Figure 8. Representative sample from subjects monitored during rapid desaturation events (SpO2 top panel, and Pulse Rate [PR], bottom panel). Masimo W1 values are recorded using red line, Apple Watch spot check values are shown as blue diamonds. When the Apple Watch could not measure SpO2 (no reading) during spot check attempt a blue "X" was placed along top of the upper panel.



The total number of valid desaturation events and the detection rate for each device under two separate test configurations are summarized in **Table 3** below. The fast desaturation detection rate is 100.0% for the Masimo W1, but only 6.1% for the Apple Watch in Configuration 1 "sleep mode" (watch face up, palm down). Whereas, the fast desaturation detection rate was also 100.0% for the Masimo W1, but only 6.7% for the Apple Watch in Configuration 2 spot check (watch face sideways, thumb facing up).

Table 3. Tabulated Summary of Fast Desaturation Events and Detection Rates for Masimo W1 vs Apple Watch

Test Configuration	Number of Subjects	Number of Valid Events	Detection Rate for Masimo W1	Detection Rate for Apple Watch
Configuration 1	7	49	49/49=100%	3/49=6.1%
Configuration 2	8	60	60/60=100%	4/60=6.7%

Detection Rate =  $(Nt / Ndesat) \times 100$  (%), Nt = Number of Detected Event by Test Device, Ndesat = Number of All Valid Fast Desaturation Events by Reference SpO2

#### Whitepaper

The Apple Watch "no read" rate was 17.3% for SpO2 spot checks during the blood desaturation study (Configuration 1 with watch facing up) and 90.4% in the fast desaturation study (Configuration 2 with watch facing sideways) see **Table 4** below. Whereas, the Masimo W1 "no read" rate was 0.0 % for both conditions; in other words, the Masimo W1 reads SpO2 100% of the time (also shown in **Table 4** below).

Table 4. Tabulated Summary of Apple Watch Orientation and No Read Rate

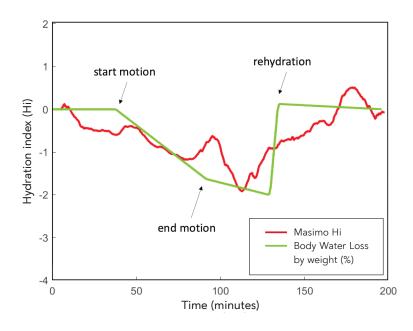
	Watch Orientation	Apple Watch No Read Rate for Spot Check Readings*	Masimo W1 No Read Rate for Spot Check Readings*
Blood Desaturation Study	Faced Up	158/912 = 17.3%	0.0% (reads continuously)
Fast Desaturation Study	Faced Side	293/324 = 90.4%	0.0% (reads continuously)

<sup>\*</sup>Note: Apple spot check readings require an individual to initiate. No Read Rate = (Nf / Nspotcheck) x 100 (%), Nf = Number of Spot Checks without Valid SpO2 (Failed for SpO2 Measurement), Nspotcheck = Number of All Spot Checks using Apple Watch

The results of the blood desaturation and fast desaturation studies demonstrate that continuous SpO2 monitoring with the Masimo W1 is highly accurate with bias and adjusted precision of 0.2% +/- 1.6% and adjusted A<sub>RMS</sub> of 1.6%. In addition, the Masimo W1 achieved a high detection rate of fast desaturation (100.0% with watch faced up and 100.0% with watch faced sideways). The blood desaturation and fast desaturation studies demonstrated that the Apple Watch has an excessive "no read" rate for SpO2 spot check measurements (17.3% and 90.4%, respectively), a low detection rate of fast desaturation (6.1% with watch faced up and 6.7% with watch faced sideways), and the adjusted A<sub>RMS</sub> of 4.6% achieved in the blood desaturation study does not meet FDA standards for clinical-grade SpO2 measurement ( $A_{RMS} \le 3\%$ ).

#### VII. HYDRATION INDEX

On December 7, 2022, Masimo announced the full market release of Hydration Index (Hi<sup>™</sup>), a powerful new tool for the Masimo W1 watch. Lack of proper hydration affects many physiological parameters, as the body works to restore homeostasis. Masimo W1 leverages such measurements to establish the hydration baseline, alerting individuals when they may be under- or over-hydrated—both of which can affect an athlete's performance capabilities. A representative example of the data plots obtained in our Masimo Laboratory of a subject undergoing a Hi trial during exercise on a treadmill and then re-hydrating by consuming water is shown in **Figure 9** (below).



## Figure 9. Hydration Index Laboratory Study

Hydration index (Hi) on Y -axis, and weight loss (dehydration) due to exercise on treadmill, and weight gain (rehydration) also shown on Y-axis. Time is displayed in minutes on the X -axis. Start and end of treadmill exercise is shown with the first two arrows, and rehydration (drinking water) is shown with third arrow going from left to right.

Masimo W1

Hydration level has been one of the most sought out parameters by athletes, vocalists, and others seeking to optimize their performance. Whether you're an elite athlete or just keen to gain more insight into your body's physiological status, Masimo W1 with Hi is a game changer.

#### VIII. EYE TO THE FUTURE

Masimo is further expanding its advanced SET® pulse oximetry solution to the consumer market with the Masimo W1 health watch, providing the benefits of medical-grade continuous pulse oximetry in a convenient, wearable device. Masimo will continue to build on its portfolio of wearable solutions with the Masimo Freedom health watch, scheduled to launch in 2023. This consumer-friendly watch will include additional features to integrate personal smartphone applications alongside Masimo's advanced continuous pulse oximetry monitoring. Future technology updates to these wearable products include the measurement of temperature, and maximum oxygen consumption (VO2Max) during exercise.

#### IX. SUMMARY

The Masimo W1 health watch is the only wearable device that provides the leading medical-grade technology to consumers in a convenient, wrist-worn device. As a health and wellness device, the Masimo W1 health watch enables individuals of all fitness levels to track their overall condition, make healthier lifestyle choices, and achieve their conditioning goals. Masimo remains committed to pursuing advanced technology that can improve the quality of life for everyone by expanding access to accurate and reliable physiological data in the home.

Whitepaper

#### X. REFERENCES

1. Castillo A, Deulofeut R, Critz A, Sola A. Prevention of retinopathy of prematurity in preterm infants through changes in clinical practice and SpO<sub>2</sub> technology. *Acta Paediatr*. 2011 Feb;100(2):188-92. doi: 10.1111/j.1651-2227.2010.02001.x. Epub 2010 Oct 15.

- 2. de-Wahl Granelli A, Wennergren M, Sandberg K, Mellander M, Bejlum C, Inganäs L, Eriksson M, Segerdahl N, Agren A, Ekman-Joelsson BM, Sunnegårdh J, Verdicchio M, Ostman-Smith I. Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39,821 newborns. *BMJ*. 2009 Jan 8;338:a3037. doi: 10.1136/bmj.a3037.
- 3. Taenzer AH, Pyke JB, McGrath SP, Blike GT. Impact of pulse oximetry surveillance on rescue events and intensive care unit transfers: a before-and-after concurrence study. *Anesthesiology*. 2010 Feb;112(2):282-7. doi: 10.1097/ALN.0b013e3181ca7a9b.
- 4. Taenzer AH, Blike GT. Postoperative Monitoring—The Dartmouth Experience. *Anesthesia Patient Safety Foundation Newsletter*. Spring-Summer 2012.
- 5. McGrath SP, Taenzer AH, Karon N, Blike G. Surveillance Monitoring Management for General Care Units: Strategy, Design, and Implementation. *Jt Comm J Qual Patient Saf.* 2016 Jul;42(7):293-302. doi: 10.1016/s1553-7250(16)42040-4.
- 6. McGrath SP, McGovern KM, Perreard IM, Huang V, Moss LB, Blike GT. Inpatient Respiratory Arrest Associated With Sedative and Analgesic Medications: Impact of Continuous Monitoring on Patient Mortality and Severe Morbidity. *J Patient Saf.* 2021 Dec 1;17(8):557-561. doi: 10.1097/PTS.00000000000000696.





Case: 24-1285 Document: 25-3 Page: 317 Filed: 01/10/2024 CONFIDENTIAL BUSINESS INFORMATION REDACTED ENTIRELY FROM PAGES MAS-ADD-394 - MAS-ADD-397

# **EXHIBIT 29**Confidential Business Information

# **EXHIBIT 30**

## UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON, D.C.

#### Before the Honorable Monica Bhattacharyya Administrative Law Judge

In the Matter of

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

## COMPLAINANTS' REQUEST FOR JUDICIAL NOTICE OF RECENT REGULATORY DEVELOPMENTS FOR MASIMO W1 WATCH

Complainants Masimo Corporation and Cercacor Laboratories, Inc. (collectively, "Masimo" or "Complainants") respectfully request that the Commission take judicial notice pursuant to 19 C.F.R. § 210.15(a)(2) and Rule 201 of the Federal Rules of Evidence of a recent regulatory determination made by the United States Food and Drug administration ("FDA") relating to Masimo's W1 Watch. The FDA's determination directly relates to the arguments raised by Apple in its pending Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal (Doc ID 807326), filed on October 30, 2023.

#### 1. Masimo W1 Is The Only FDA-Cleared Over-The-Counter Pulse Oximeter

On November 17, 2023, the FDA notified Masimo of 510(k) clearance of the Masimo W1 for both prescription and over-the-counter use. *See* Appendices A (Notification Letter), B (Indications for Use), C (510k Summary). As a result of this clearance, the Masimo W1 Watch is the only FDA-cleared over-the-counter pulse oximeter on the market.

Judicial notice is appropriate because the FDA's determination only recently issued and is not subject to reasonable dispute because it can be accurately and readily determined from sources whose accuracy cannot be questioned. Fed. R. Evid. 201(b)(2).

#### 2. The FDA's Determination Rebuts Apple's Assertions In The Investigation

The 510(k) clearance directly rebuts Apple's proclamations in its Motion to Stay that "[Masimo's] watch product in particular remains largely a fairy tale," that "[Masimo's] purported domestic industry was and remains a fiction," and its characterization of the Masimo Watch as "an imaginary product." Doc. ID 807326 at 1, 7, 22. It is also relevant to Apple's argument that there will be no significant harm to Masimo if a stay is granted, because Apple supported that argument by pointing to the lack of FDA clearance for the W1. *See id.* at 20-21.

For these reasons, Masimo respectfully requests that the Commission take judicial notice of Appendices A-C submitted herewith.

Dated: November 20, 2023 By: /s/ Sheila N. Swaroop

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Counsel for Complainants Masimo Corporation and Cercacor Laboratories, Inc.

#### APPENDIX LIST OF ATTACHMENTS

Appendix Letter	Description
A	FDA Notification Letter regarding Masimo W1 <sup>TM</sup>
В	Masimo W1 <sup>TM</sup> Indications for Use
С	Masimo W1 <sup>TM</sup> 510(k) Summary

# APPENDIX A



November 17, 2023

Masimo Corporation Sindura Penubarthi Associate Director, Regulatory Affairs 52 Discovery Irvine, California 92618

Re: K232512

Trade/Device Name: Masimo W1 Regulation Number: 21 CFR 870.2340 Regulation Name: Electrocardiograph

Regulatory Class: Class II

Product Code: DPS, DQA, DXH

Dated: October 23, 2023 Received: October 23, 2023

#### Dear Sindura Penubarthi:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<a href="https://www.fda.gov/media/99812/download">https://www.fda.gov/media/99812/download</a>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<a href="https://www.fda.gov/media/99785/download">https://www.fda.gov/media/99785/download</a>).

K232512 - Sindura Penubarthi

Page 2

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <a href="https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products">https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products</a>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems">https://www.fda.gov/medical-device-problems</a>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<a href="https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance">https://www.fda.gov/training-and-continuing-education/cdrh-learn</a>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<a href="https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</a>) for more information or contact DICE by email (<a href="DICE@fda.hhs.gov">DICE@fda.hhs.gov</a>) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

## APPENDIX B

### DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

#### **Indications for Use**

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023 See PRA Statement below.

Submission Number (if known)	
K232512	
Device Name	
Masimo W1	

Indications for Use (Describe)

Masimo W1™ and the integrated Masimo W1 module are intended for the spot-check determination of Heart Rate using a single-channel electrocardiogram (ECG). The Masimo W1 and the integrated Masimo W1 module records, stores, transfers, and displays the single-channel ECG for the manual interpretation of heart rate. It is worn on the wrist and also provides other continuous parameters technologies (e.g., pulse oximetry).

The Masimo W1<sup>™</sup> and the integrated Masimo W1 module are also intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The Masimo W1 and the integrated Masimo W1 Module are indicated for adults in hospitals, clinics, long-term care facilities, and homes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

#### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## APPENDIX C



#### 510(k) Summary K232512

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	November 17, 2023
Contact:	Sindura Penubarthi Associate Director, Regulatory Affairs Masimo Corporation Phone: (949) 396-4041
Trade Name:	Masimo W1
Common Name:	Electrocardiograph
Classification Regulation/ Product Code:	21 CFR 870.2340, Class II/DPS
Additional Product Codes:	DQA DXH
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	New Device
Predicate Device:	K201456 – Withings Scan Monitor
Reference Device:	K221260 – CSF-3

#### 1.0 Device Description

The Masimo W1 is a watch that incorporates the W1 Module, which is the device that is responsible for the physiological signal detection and algorithm in providing the supported parameters. The module incorporates ECG functionality for Heart Rate Monitoring and Masimo SET Pulse Oximetry technology so that it can provide both ECG (Heart Rate parameter) and Masimo SET Pulse Oximetry parameters. The parameter output from the W1 Module is displayed on the touchscreen watch interface.

As part of the Masimo W1 watch, the Masimo W1 Module is integrated into the Masimo W1 watch platform, which consists of a typical IT hardware platform to enable other non-medical smart watch features (e.g., step counting, walking, running, fall detection and rise to wake).

See Table 1 below for the Masimo W1 Specifications.

Table 1 - Specifications	
Feature	Specifications
Continuous Display of Parameter Data	Yes
User Interface	Touchscreen



#### 510(k) Summary K232512

Table 1 - Specifications		
Feature	Specifications	
Performance Specifications		
SpO2, No Motion/ Low Perfusion (70-100%)	2% adults	
Pulse Rate, No Motion (25-240 bpm)	3 bpm adults	
Heart Rate (25-240 bpm)	≤ 5 bpm adults	
Electrical Specifications		
Battery	Internal Rechargeable Li-Ion	
Mechanical Specifications		
Size	40 mm (1.57")	
Display Type	Touchscreen	
Weight	54 g (including watchband)	
Environmental Specifications		
Operating Temperature	0 to 35 °C (32 to 95°F)	
Operating Humidity	10% to 95% RH (non-condensing)	
Storage/Transport Temperature	-20°C to 60°C (-4°F to 140°F)	
Storage/Transport Humidity	10% to 95% RH (non-condensing)	
Classificat	tion per IEC 60601-1	
Electrical Safety	IEC 60601-1	
EMC	IEC 60601-1-2	
Electrical Isolation Type	Internally Powered	
Applied Part Type	CF Applied Part	
Ingress Protection	IP24	
Mode of Operation	Continuous	

#### 2.0 Intended Use/ Indications for Use

Masimo W1<sup>TM</sup> and the integrated Masimo W1 module are intended for the spot-check determination of Heart Rate using a single-channel electrocardiogram (ECG). The Masimo W1 and the integrated Masimo W1 module records, stores, transfers, and displays the single-channel ECG for the manual interpretation of heart rate. It is worn on the wrist and also provides other continuous parameters technologies (e.g., pulse oximetry).

The Masimo W1<sup>TM</sup> and the integrated Masimo W1 module are also intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The Masimo W1 and the integrated Masimo W1 Module are indicated for adults in hospitals, clinics, long-term care facilities, and homes.

#### 3.0 Technological Characteristics

Principle of Operation

Electrocardiogram (ECG)

The ECG feature on Masimo W1 relies on the principle that the electrical signals can be detected as different parts of the heart contract and relax during a cardiac cycle allowing the detection of heart activity and for the estimation of heart rate (HR). The change in polarization of the heart muscles creates electrical signals that are propagated so that they can be detected at the skin surface of the wrist.

Pulse Oximetry-Based Parameters



#### 510(k) Summary K232512

The Masimo SET pulse oximeter technology relies on the Beer-Lambert law and the following principles of pulse oximetry:

- Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
- The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Mechanism of Action for Achieving the Intended Effect

The Masimo W1 watch achieves its intended effect through the integrated Masimo W1 Module that provides both the electrical and optical sensing technology and parameter algorithms. The W1 Module is integrated into the W1 watch so that the sensing components contact the skin on the wrist. The top of the watch is provided with an electrical sensing pad that is contacted by the two fingers on the opposing hand. Contacting the electrical sensing pad allows for the detection of the ECG signal when the ECG feature is activated on the watch touchscreen. Once the ECG feature is activated, it detects and calculates the heart rate.

The Masimo SET pulse oximetry-based parameters are supported by the W1 Module's optical sensing components located on the bottom of the module that contacts the skin on the wrist. The W1 Module continuously detects and processes the optical signals that change with the transmission of LED light into the wrist tissue. The W1 Module utilizes multiple wavelengths of light and advanced signal processing techniques to isolate the arterial signal from other static factors (e.g., skin pigment) to establish the ratio used in the estimation of the SpO2. The pulse rate is determined by the periodic changes in the photoplethysmograph (PPG). The parameters are then continuously updated and displayed on the watch so that it can be viewed, recorded, and/or transferred. The use of the Masimo W1 watch can be discontinued by taking off the watch or deactivating the continuous parameters from the watch's touchscreen.

#### 4.0 Summary of Technological Characteristics of Subject Device Compared to Predicate Device

Similarities and Differences between Predicate and Subject Device

The subject device, Masimo W1, and the predicate device, Scan Monitor (K201456), have the following key similarities:

- Both devices have the same intended use;
- Both devices rely on the same principles of operation;
- Both devices are indicated for the same population of prescription and OTC users;

The subject device, Masimo W1, and the predicate device, Scan Monitor (K201456), have the following key differences:

- The subject device does not support ECG rhythm classifications (e.g., AFib);
- The subject device continuously updates pulse oximetry parameter data.



#### 510(k) Summary K232512

The subject device and predicate devices were found to have the same intended use without any technological differences that raise different questions of safety and effectiveness.



## 510(k) Summary K232512

Feature 510(k) Number	Masimo W1 Subject Device	Withings Scan Monitor Primary Predicate (K201456)	Comparison to Predicate Device
General Information			
Classification Regulation/ Product Code	21 CFR 870.2340, Class II/DPS	21 CFR 870.2340, Class II/DPS	Same
Product Code(s)	DQA DXH	DQA DXH	Same
Indications for Use	Masimo W1 <sup>TM</sup> and the integrated Masimo W1 module are intended for the spot-check determination of Heart Rate using a single-channel electrocardiogram (ECG). The Masimo W1 and the integrated Masimo W1 module records, stores, transfers, and displays the single-channel ECG for the manual interpretation of heart rate. It is worn on the wrist and also provides other-continuous parameters technologies (e.g., pulse oximetry). The Masimo W1 <sup>TM</sup> and the integrated Masimo W1 module are also intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The Masimo W1 and the integrated Masimo W1 Module are indicated for adults in hospitals, clinics, long-term care facilities, and homes.	The Scan Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Scan Monitor also displays ECG rhythms and detects the presence of atrial fibrillation (when the monitor is prescribed or used under the care of a physician). The Scan Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals.  The Scan Monitor is also indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2). The Scan Monitor is intended for spot-checking of adult patients in hospitals, clinics, long-term care facilities and homes.	Similar. The subject device has similar indications as the predicate for ECG HR and Pulse Oximetry
	Technological Characteristics	aracteristics	

K232512 Page 5 of 11



# **510(k)** Summary K232512

Feature 510(k) Number	Masimo W1 Subject Device	Withings Scan Monitor Primary Predicate (K201456)	Comparison to Predicate Device
Principles of Operation	The W1 Module software analyzes the patterns in the ECG waveform to determine manual interpretation of Heart Rate.  The Masimo SET pulse oximeter technology relies on the Beer-Lambert law and the following principles of pulse oximetry:  Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).  The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as	The iECG software analyzes the patterns in the ECG waveform to determine different types of known heart activity (e.g., Heart Rate, Atrial Fibrillation).  Scan Monitor pulse oximetry technology relies on the differential absorption by blood of red (660nm) and infrared light (940nm) which relies on the Beer-Lambert law for the principles of pulse oximetry.	Similar. The subject device utilizes the same principles related to ECG and Pulse Oximetry.
Supported Measured Parameters	well. HR, SpO2, PR	HR, SpO2	Different. The subject device provides additional pulse oximetry-based features (i.e., PR).  Testing is provided to support the PR performance.

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# **510(k)** Summary **K232512**

Feature 510(k) Number	Masimo W1 Subject Device	Withings Scan Monitor Primary Predicate (K201456)	Comparison to Predicate Device
Supported Calculated features	Pi	HRV, AFib Classification	Different. The subject device provides Pi.  Testing is provided to
User Interface	Touchscreen	Touchscreen	Same
SpO2 (70-100%)	Performance Specifications (Arms)  2%, adults (No Motion/ Low Perfusion)  3%, adults (No	fications (Arms)  3%, adults (No Motion)	Different. Subject device includes performance testing to support
Pulse Rate (25-240 bpm)	3 bpm	Not supported	Different. Subject device includes performance testing to support improved specification.
Heart Rate (25-240 bpm)	5 bpm	Not Known	Testing is provided to support the specification.
Battery	Internal Rechargeable Electrical Specifications	cifications Internal Rechargeable	Same
	Mechanical Specifications	ecifications	
Watch Face Size	40 mm (1.57")	38 mm or 42 mm	Similar. Testing is provided to support the substantial equivalence.
Weight	54 g (including watchband)	58 gms or 83gms	Similar. The weight difference is minor and is consistent with other marketed watches.
	Environmental Specifications	<b>Specifications</b>	

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## 510(k) Summary K232512

Feature 510(k) Number	Masimo W1 Subject Device	Withings Scan Monitor Primary Predicate (K201456)	Comparison to Predicate Device
Operating Temperature	0 to 35 °C (32 to 95°F)	-10 to 45 °C (14 to 113°F)	Similar. Testing is provided to support the specification.
Operating Humidity	10% to 95%, non-condensing	Not Known	Testing is provided to support the specification.
Storage/Transport Temperature	$-20 \text{ to } 60^{\circ}\text{C} \text{ (-4 to } 140^{\circ}\text{F)}$	-20 to 85°C (4 to 185°F)	Similar. Testing is provided to support the specification.
Storage/Transport Humidity	10% to 95%, non-condensing	Not Known	Testing is provided to support the specification.
	Classification per IEC 60601-1	IEC 60601-1	
Electrical Safety	IEC 60601-1	IEC 60601-1	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Ingress Protection	IP24	Not Known.	Testing is provided to support the specification.
Mode of Operation	Continuous	Continuous	Same

K232512 Page 8 of 11



#### 510(k) Summary K232512

#### 5.0 Performance Data

The following non-clinical testing was provided to support the non-parameter specifications and the substantial equivalence of the subject device.

- Biocompatibility in accordance with ISO 10993-1
- EMC testing per IEC 60601-1-2
- Electrical safety testing per IEC 60601-1
- Environmental and Mechanical testing
- Cleaning Validation
- Software verification and validation testing per FDA Software Guidance
- Human Factors Usability testing per FDA Human Factors and Usability Guidance

The following are the list of standards that were used as part of the evaluation:

- IEC 60601-1:2005/2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2013
- IEC 60601-1-11:2015
- IEC 60601-2-27:2011
- IEC 60601-2-47:2012
- ISO 80601-2-61:2017
- ISO 10993-1:2018
- IEC 62304:2015
- IEC 62366-1:2015

#### **Performance Bench Testing**

Performance bench testing for the Masimo W1 is included in this submission to support both ECG HR and Pulse Oximetry based parameter performance.

#### **Biocompatibility Testing**

Biocompatibility testing in accordance with ISO 10993-1 is included as part of this submission to support the acceptability of the biocompatibility risks.

#### Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

EMC testing was conducted in accordance with IEC 60601-1-2: 4.1 Edition and the electrical safety in accordance with the IEC 60601-1 standard. Environmental, mechanical, cleaning, and chemical resistance testing was also provided to support the substantial equivalence of the Masimo W1.

#### **Software Verification and Validation Testing**

Software verification and validation testing were conducted, and documentation was provided as



#### 510(k) Summary K232512

recommended by FDA Guidance for the Content of Premarket Submissions for Software Device Software Functions, June 2023. The software was found to fit in the category of products that would require Basic Documentation Level because the failure or latent flaw of the device software function would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device or others in the environment of use prior to the implementation of the risk controls. The software does not provide any data that is considered life supporting.

#### **Human Factors Usability Testing**

To support the usability of the Masimo W1, human factors and usability risks were evaluated to be acceptably mitigated in accordance with FDA Guidance, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design*, dated February 3, 2016. The testing was found to support acceptability of the human factors and usability risks.

#### **Clinical Performance Testing**

To support the performance of the Masimo W1, clinical data is provided to support of the performance of the Masimo W1. To address potential concerns related to skin pigment discrepancies in pulse oximetry, the SpO2 clinical testing included 31 subjects with varying skin pigmentations measured using a color-based scale, Massey-Martin. The results separated by skin pigment supported the performance of the Masimo W1 across different skin tones.

The SpO2 performance testing was conducted in accordance with the ISO 80601-2-61. The prospective clinical study included 31 healthy volunteer subjects, including 13 light, 12 medium and 6 dark pigmented subjects, which exceeded the ISO 80601-2-61 minimum sample size requirements and the minimum number of dark pigmented subjects in accordance with the FDA Guidance for Pulse Oximeters. Subjects were classified as dark and light based upon their Massey-Martin scores, 1-3 classified as "Light", 4-6 classified as "Medium" and 7-10 as "Dark" or subjects with more skin pigment.

The overall performance was 1.62% Arms after adjusting for repeated measures. The results support the specification of 2% Arms across the range of 70%-100% SaO2. The breakdown of the performance for dark, medium, and light subjects is provided below.

Pigmentation	Bias	Precision	A <sub>RMS</sub>	Adjusted Precision	Adjusted A <sub>RMS</sub>	Adjusted LOA	Nsubj	Npairs
Dark (Massey 7-10)	0.37	1.64	1.68	1.78	1.82	[-3.14, 3.88]	6	329
Medium (Massey 4-6)	-0.26	1.58	1.60	1.65	1.67	[-3.49, 2.97]	12	724
Light (Massey 1-3)	0.56	1.41	1.51	1.48	1.58	[-2.34, 3.46]	13	831

To clinically validate the performance of the heart rate (HR) feature on the Masimo W1 watch, a prospective clinical study was conducted on 61 subjects where the spot-check HR measurements obtained



#### 510(k) Summary K232512

from the W1 module were compared to an FDA cleared ECG reference measurement. The testing supported the claimed heart rate performance and its substantial equivalence.

To clinically validate the ECG waveform quality of the Masimo W1, the ECG waveforms collected by the Masimo W1 were compared to Lead I of a gold standard reference of a 12-Lead ECG by three board certified cardiologists. The testing supported the acceptability of the detected ECG waveforms.

#### 6.0 Conclusion

The data supported the substantial equivalence of the Masimo W1.

#### In the Matter of Certain Light-Based Physiological Measurement Devices and Components Thereof Inv. No. 337-TA-1276

#### **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on November 20, 2023, I caused copies of the foregoing document to be filed and served as indicated below:

Secretary – U.S. International Trade Commission	
The Honorable Lisa R. Barton Secretary to the Commission U.S. International Trade Commission 500 E Street, SW, Room 112 Washington, DC 20436	<ul><li>✓ Via Electronic Filing [EDIS]</li><li>☐ Via hand delivery</li><li>☐ Via Express Delivery</li><li>☐ Not filed</li></ul>
Administrative Law Judge – U.S. International Trad	e Commission
The Honorable Monica Bhattacharyya U.S. International Trade Commission 500 E Street, S.W., Room 317 Washington, D.C. 20436	☑ Via E-mail to edward.jou@usitc.gov and Bhattacharyya337@usitc.gov
Counsel for Respondent Apple, Inc.	
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November 20, 2023

/s/ Claire A. Stoneman

Claire A. Stoneman Litigation Paralegal Knobbe, Martens, Olson & Bear, LLP

## **EXHIBIT 31**

CISCO
The bridge to possible

Evaluating management platforms for your IT infrastructure?

Get IDC analyst perspective



When it comes to enterprise AI,

size matters.

CLOUDERA

Artificial Intelligence 

Security 

Data Infrastructure 

Automation 

Enterprise Analytics 

More 

Apple's former top lawyer: \$1
billion budget enabled highrisk strategies

f X in



Image Credit: Before You Take the LSAT

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## Realizing AI transformation

Top tech industry leaders weigh in on what it takes to build, scale and secure  $\Delta I$ 

Catch up here

Former Apple general counsel <u>Bruce Sewell</u> led the company's legal department for eight years, seeing the company through major lawsuits such as the <u>iBooks antitrust case</u> and <u>Samsung's smartphone patent trial</u>. Now he's speaking openly about how Apple has strategically embraced high-risk legal strategies to gain competitive advantages — using a gigantic legal budget to back business decisions that could result in highly favorable or unfavorable outcomes.

Having retired from Apple in 2017, Sewell spoke candidly with Columbia Law School student Doreen Benyamin for a YouTube series titled "Before You Take the LSAT" (via AppleInsider), designed to help prospective lawyers know what they're getting into before they apply to law schools. In the video, Sewell explained that his job at Apple was not to stay clear of the line dividing legally risky actions from clearly safe actions, but rather to "steer the ship as close to that line as you can, because that's where the competitive advantage lies ... you want to get to the point where you can use risk as a competitive advantage." A legal team becomes an asset to a company when it can help it venture as close to a blurry legal/illegal line as possible, he said, and then manage the "nuclear" situation if it gets into trouble.

Putting AI to Work with Matt Marshall

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https://venturebeat.com/mobile/apples-former-top-lawyer-1-billion-budget-enabled-high-risk-strategies/



Sewell suggested that the keys to a high-risk legal strategy's success are proper funding and executive support. When he retired, the company had a staggering annual legal budget of \$1 billion — enough to support 350 lawyers simultaneously working on a single big case, such as the Samsung trial, which involved reviewing around 8 million documents and 200,000 billable hours of labor, to say nothing of the company's other cases. Apple CEO Tim Cook backed the lawyers through thick and thin, which Sewell said was important "because every so often, you're going to get it wrong."

The "very ugly" iBooks lawsuit, which saw the U.S. government sue Apple and book publishers for fixing prices during the launch of the iPad's iBookstore, was a critical example of getting it wrong, Sewell noted. While he believed Apple's conduct had been innocent, "there were some things going on amongst a group of publishers that I didn't know about ... But, in the end, I got it wrong. Apple ended up being sued by the government and having to pay a large fine." Yet Cook was reassuring, saying Sewell had made the best choice he could with the information he had:

You didn't know about these other things. Don't let that scare you. I don't want you to stop pushing the envelope because that's why legal is an important function in the company.



While "pushing the envelope" may represent a viable corporate legal strategy, it explains some of the less savory elements of the company's business practices, namely acting in ways that — legal or not — may run afoul of moral or ethical standards and using its cash pile to dissuade or intimidate smaller entities from enjoying their own legal rights. As just one example, Apple has been warned by multiple regulators over <u>misleading warranty repair practices</u> and <u>in some cases has told customers</u> in so many words that they'll have to sue the nearly \$1 trillion company to obtain repairs.

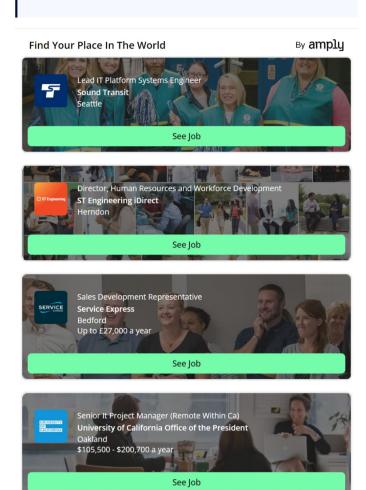
The company has also faced <u>international criticism over tax payments</u> that rode the fine edge of legality while denying revenues to countries where it does business. While maintaining that it hadn't done anything wrong, Apple

https://venturebeat.com/mobile/apples-former-top-lawyer-1-billion-budget-enabled-high-risk-strategies/

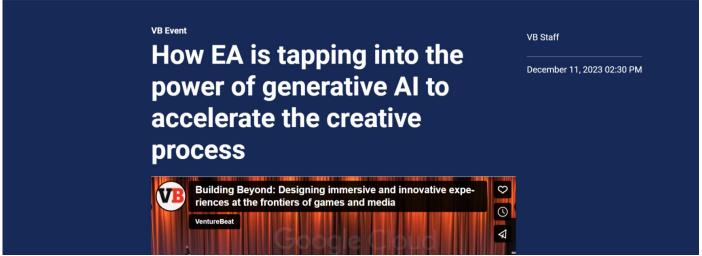
reluctantly agreed to pay over \$15 billion in back taxes and fines to the European Union pending an appeal. More recently, Apple initiated a massive international legal battle against Qualcomm in an effort to drive down patent licensing fees, but settled early in the trial.

01/02/2024

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## **EXHIBIT 32**

Case: 24-1285 Document: 25-3 Page: 346 Filed: 01/10/2024

Case 8:20-cv-00048-JVS-JDE Document 1801-7 Filed 06/26/23 Page 2 of 11 Page ID #:153943

From: "Sara Tavakoli" <sara\_tavakoli@apple.com>

Received(Date): Thu, 06 Aug 2020 19:52:41 +0000

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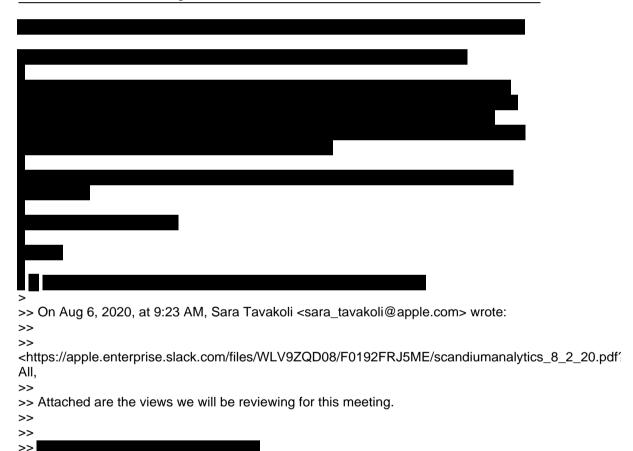
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<sankalita.saha@apple.com>,"Ravi RTK Katragadda"

<ravi\_katragadda@apple.com>

**Attachment:** 

**Date:** Thu, 06 Aug 2020 19:52:41 +0000





>>

I	
	On Aug 6, 2020, at 9:23 AM, Sara Tavakoli < sara tavakoli@apple.com > wrote:
	Hi All,
	Attached are the views we will be reviewing for this meeting.
	Scheduled: Aug 6, 2020 at 1:00 PM to 1:45 PM Location: Virtual Conference One-Time Room Invitees: Sara Tavakoli, Steve Waydo, Evan Doll, Abby Lee, Andrew Garber, Joelle Lam, Siddesh Koppalada-Shivakumaraswamy, David Fang, Marc Schonbrun, Vera Carr, Sankalita Saha, Ravi Katragadda — Recommended Options —
	Join or start from Webex:
	https://appleinc.webex.com/appleinc/j.php?MTID=m43f196552a65deb18d0f469c2fe38c
	Dial from video system [AVCN]: Enter the Meeting ID: 1460611599
	—— Additional Options ——
	Join from Cisco Jabber:
	sip://1460611599@appleinc.webex.com
	Join by phone (charges may apply):
	tel://+14156550003,,1460611599,,,#
	Global call-in numbers:
	https://appleinc.webex.com/cmp3300/webcomponents/widget/globalcallin/globalcallin.de

## **EXHIBIT 33**

#### UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

Inv. No. 337-TA-1266

CERTAIN WEARABLE ELECTRONIC DEVICES WITH ECG FUNCTIONALITY AND COMPONENTS THEREOF

RESPONDENT APPLE INC.'S EMERGENCY MOTION TO SUSPEND ANY REMEDY OR EXTEND THE TARGET DATE AND STAY PROCEEDINGS PENDING RESOLUTION OF ANY APPEAL OF THE PATENT OFFICE'S DECISION THAT UNITED STATES PATENT NOS. 10,638,941, 10,595,731, AND 9,572,499 ARE UNPATENTABLE.

#### **INTRODUCTION**

On December 6, 2022, the Patent Trial and Appeal Board ("PTAB") issued Final Written Decisions holding unpatentable all asserted claims of the three patents at issue in this Investigation: United States Patent Nos. 10,638,941 ("the '941 patent'"), 10,595,731 ("the '731 patent), and 9,572,499 ("the '499 patent"). The PTAB's Final Written Decisions are appended to this Motion.

In light of the PTAB's recent orders, Respondent Apple Inc. ("Apple") respectfully petitions the Commission to suspend any remedial orders or, in the alternative, extend the December 12, 2022 Target Date of its Final Determination and stay all proceedings prior to issuance of any Final Determination pending final resolution of any appeal of the PTAB's decisions. A suspension is consistent with the Commission's routine past practice. A stay will simplify the issues and conserve agency and party resources—by avoiding issuance of a merits determination that is likely to be mooted by an affirmance of the PTAB's Final Written Decisions—without causing any harm to Complainant. And either a suspension or a stay accords due deference to the Patent Office's role as the lead agency in assessing patentability and honors Congress's intent that invalid patents should not be enforced.

Given the short time until the Commission's December 12, 2022 Target Date, Apple asks that the Commission consider this Motion on an emergency basis.<sup>1</sup>

#### **FACTS**

This Investigation concerns three heart-health monitoring features of Apple Watch: the ECG app, Irregular Rhythm Notification ("IRN"), and High Heart Rate Notification ("HHRN"). The ECG app enables users to take electrocardiograms to determine whether they are experiencing atrial fibrillation ("AFib"), a potentially life-threatening heart condition that afflicts millions in the United States. IRN monitors the regularity of users' heart rates to identify signs consistent with AFib. HHRN informs users

1

<sup>&</sup>lt;sup>1</sup> Counsel for Apple contacted counsel for Complainant and for the Office of Unfair Import Investigations ("OUII") regarding this Motion. Complainant has not yet indicated its position on this Motion and will provide its position after it sees the Motion. Counsel for OUII support the motion to the extent that it asks the Commission to suspend enforcement of any remedial orders pending appeal of the PTAB's Final Written Decisions, but otherwise oppose the Motion. The Commission may wish to extend the Target Date for a Final Determination to allow sufficient time for full briefing and consideration of this Motion.

First, a suspension or stay "recognizes the [Patent Office's] role as the lead agency in assessing patentability, or validity, of proposed or issued claims" by ensuring that the Commission does not contradict the PTAB's unpatentability determinations. Unmanned Aerial Vehicles, 2020 WL 5407477, at \*21 (citing Fresenius USA, Inc. v. Baxter Int'l Inc., 721 F.3d 1330, 1339, 1334 (Fed. Cir. 2013)); see also Magnetic Tape Cartridges, 2019 WL 2635509, at \*38 n.23; Three-Dimensional Cinema, 2016 WL 7635412, at \*37. Congress and the courts have long recognized that the Patent Office is the lead federal agency for determining patentability. See Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1427 (Fed. Cir. 1988). Congress has further emphasized the Patent Office's leadership and expertise on matters of patentability when it established the PTAB as part of the America Invests Act. See S. Rep. No. 110-259, at 5, 23 (2008); 35 U.S.C. §§ 6(a), (b)(4). In contrast, Congress has made clear that § 337 is a "trade statute," not a patent statute. Suprema, Inc. v. Int'l Trade Comm'n, 796 F.3d 1338, 1344-45 (Fed. Cir. 2015) (en banc). Unlike the PTAB, which can formally cancel a patent claim after its unpatentability decision has been finally resolved, see 35 U.S.C. § 318(b), the Commission's determinations on patent validity "are for purposes of adjudicating whether or not a Section 337 violation has occurred, and are not binding on the [Patent Office], federal courts, or other tribunals, even if affirmed by the Federal Circuit," Unmanned Aerial Vehicles, 2020 WL 5407477, at \*21 (citing Hyosung TNS Inc. v. Int'l Trade Comm'n, 926 F.3d 1353, 1358 (Fed. Cir. 2019)); see Tex. Instr. Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1568-69 (Fed. Cir. 1996) ("The Commission's findings neither purport to be, nor can they be, regarded as binding interpretations of the U.S. patent laws in particular factual contexts." (quoting S. Rep. No. 93-1298, at 196 (1974)). The Patent Office recently emphasized these differences between the two agencies in explaining why it "no longer discretionarily denies petitions based on ... parallel ITC proceeding[s]." Interim Procedures for Discretionary Denials, U.S. Patent & Trade Office (June 21, 2022), https://tinyurl.com/mwvyajej.

Second, a suspension or stay would "give[] effect to the Congressional goal" regarding the IPR procedure under the America Invents Act. *Unmanned Aerial Vehicles*, 2020 WL 5407477, at \*21. Congress intended IPRs to "provide 'a quick, inexpensive, and reliable alternative to district court litigation to resolve questions of patent validity." *Id.* (quoting S. Rep. No. 110-259, at 20); *see also SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1352 (2018) (explaining that IPRs "allow[] private parties to challenge previously issued patent

## **EXHIBIT 34**

Case 1:22-cv-01377-MN-JLH Document 50 Filed 02/10/23 Page 1 of 29 PageID #: 6035

### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

APPLE INC.,	)
Plaintiff,	) ) ) C.A. No. 22-1377-MN
V.	) C.A. 100. 22-1377-WIN
	) JURY TRIAL DEMANDED
MASIMO CORPORATION and SOUND UNITED, LLC,	)
Defendants.	) PUBLIC VERSION
MASIMO CORPORATION,	<u> </u>
,	)
Counter-Claimant,	ĺ
V.	)
	)
APPLE INC.,	)
	)
Counter-Defendant.	)

## PLAINTIFF APPLE INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR AN EXPEDITED TRIAL

OF COUNSEL:

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Dated: February 3, 2023 10580656 / 12209.00051

Public Version Dated: February 10, 2023

David E. Moore (#3983) Bindu A. Palapura (#5370) Andrew L. Brown (#6766)

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Attorneys for Plaintiff/Counter-Defendant Apple Inc.

Case 1:22-cv-01377-MN-JLH Document 50 Filed 02/10/23 Page 2 of 29 PageID #: 6036

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#### **INTRODUCTION**

Pursuant to Federal Rules of Civil Procedure 1 and 16, Plaintiff Apple Inc. ("Apple") respectfully requests an expedited trial to adjudicate Apple's claims against Defendants Masimo Corporation and Sound United, LLC (together, "Masimo") for willful patent infringement of Apple's patented designs related to Apple Watch and its charger. Apple brings the present motion in lieu of a motion for a preliminary injunction to conserve Court and party resources.

An expedited trial will mitigate the significant irreparable harms that Apple will suffer in the second half of 2023 when, as Masimo admits, Masimo plans to significantly increase sales of its "W1" watch, which copies Apple's iconic patented designs, by distributing it to consumers through some of the same retail channels through which Apple Watch is currently sold. Expediting trial is feasible here because the scope of the issues for trial is narrow and only limited discovery and pre-trial proceedings are necessary. For the reasons herein, Apple respectfully requests an expedited trial approximately eight months from a decision on this motion.

#### **NATURE AND STAGE OF THE PROCEEDINGS**

On October 20, 2022, Apple sued Masimo for direct and willful infringement of four design patents related to smart watches and smart watch chargers, namely U.S. Patent Nos. D735,131; D883,279; D947,842; and D962,936 (together, "the Patents-in-Suit"). *See* D.I. 1 ("Complaint"). On December 12, 2022, Masimo answered the Complaint, and Sound United moved to dismiss Apple's claims of direct and willful infringement. D.I. 29; D.I. 30; D.I. 31.

#### **SUMMARY OF THE ARGUMENT**

1. An expedited trial in this case is necessary to significantly mitigate irreparable harms to Apple caused by Masimo's willful infringement and would not unduly prejudice Masimo. Masimo admits that as soon as the *second half of 2023*, it plans to expand sales of its W1 watch, which copies the iconic patented designs of Apple Watch, as well as forthcoming smart watches

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that Masimo has suggested will use the same infringing design, through some of the *same retail channels through which Apple Watch is currently sold*. In the absence of an expedited trial and subsequent post-trial relief enjoining Masimo's willful infringement, Apple will be forced to compete against its own patented designs in Masimo's copy-cat product in some of those same retail channels. That infringing competition will result in irreparable harms to Apple including: (1) lost market share; and (2) damage to Apple's reputation as an innovator of distinctive designs and a provider of high-quality products. *See* Section I.A. An expedited trial on liability will significantly mitigate those harms by expediting Apple's anticipated request for post-trial injunctive relief, which Apple is likely to obtain. *See* Section I.B.

- 2. Masimo, on the other hand, will suffer no undue prejudice from the expeditious adjudication of this case. In fact, the prompt resolution of liability will benefit both parties by providing certainty as to Apple's claims of infringement. *See* Section II.
- 3. Expediting trial is feasible given the narrow scope of this case. Apple's claims are limited to infringement of *design* patents (rather than utility patents) by a single product (W1 and its charger). Consequently, only limited discovery and pretrial proceedings will be required, and the scope of liability issues at trial will be narrow. *See* Section III.A. Bifurcation of damages issues would further streamline the expedited trial to the time-sensitive issue of liability, which is necessary for Apple to obtain post-trial injunctive relief. *See* Section III.B.

unfair gain of share in any relevant market in which W1 and Apple Watch compete because of Masimo's infringing W1 sales.

<sup>&</sup>lt;sup>1</sup> Although Apple disputes Masimo's definition of an alleged relevant United States market for the sale of "health watches" in its antitrust counterclaims in *Apple Inc. v. Masimo Corp. et al.*, No. 1:22-cv-01378-MN, D.I. 15 (D. Del. Dec. 14, 2022), there is no dispute that W1 will compete with Apple Watch for customers. As described herein, Apple will be irreparably harmed by Masimo's unfair gain of share in any relevant market in which W1 and Apple Watch compete because of

#### FACTUAL BACKGROUND

## I. APPLE REVOLUTIONIZED SMART WATCHES THROUGH ITS INNOVATIONS AND INVESTMENTS IN APPLE WATCH.

Apple was instrumental in developing consumer interest in smart watch products through its innovations in the design and marketing of Apple Watch. Malackowski ¶¶ 32–33. Through Apple's significant investment of time and money, Apple designed Apple Watch so that customers would want to buy, wear, and visually appreciate it as an ornamental watch—not just as a piece of new technology. Jue ¶ 5; Russell-Clark ¶ 5. Apple's innovations include the rear design of Apple Watch. *Id.* As an homage to traditional luxury watches, which often include a fully or partially transparent back so that the consumer can see the high-quality internal mechanisms, Apple's industrial design team designed a back for Apple Watch that provides an aesthetically pleasing hint of the high-quality mechanisms lying within. Russell-Clark ¶ 7. Apple patented those designs in D883,279, D947,842, and D962,936 (together, "the Watch Patents"),² among others, and continues to use its patented designs in its latest Apple Watch products. Ball ¶¶ 66–71, 111–23.

Apple has also invested significant resources in marketing Apple Watch, including to foster in consumers' minds an association with Apple as a brand. Jue ¶ 4; Russell-Clark ¶ 6. That association is so strong that Apple's advertisements often feature only an image of Apple Watch. *See, e.g.*, Ex. A; Jue ¶ 7. Apple Watch's rear design is one factor in consumer decisions to purchase Apple Watch. Jue ¶ 10; Malackowski ¶¶ 34–44; Simonson ¶¶ 33–34.

#### II. MASIMO'S W1 COPIES APPLE'S PATENTED DESIGNS.

Masimo is a medical device company that, prior to August 2022, had never offered a smart watch in its 33-year history. *See* Malackowski ¶ 48. Masimo's primary business is and always

<sup>&</sup>lt;sup>2</sup> Apple also patented the unique design of the Apple Watch charger, which is sold with Apple Watch, in D735,131 ("the charger Patent").

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has been selling devices to hospitals for monitoring various patient biometrics—none of which are at issue here. *Id.* at ¶ 46. Recently, however, Masimo witnessed strong consumer interest in Apple Watch, including its beautiful design. Desperate not to be left out, Masimo released W1 in the United States on August 31, 2022. D.I. 31, ¶ 39. But rather than developing its own designs, Masimo simply copied the iconic, patented designs embodied in Apple Watch:



Critically, the patented Apple designs Masimo copied include the designs of the back of W1, which contains windows to its physiological sensor. Masimo heavily features W1's back design in product advertisements. The back of the watch is the largest image on W1's webpage:



Ex. C. And numerous other images from Masimo emphasize W1's back design. *Id.* Masimo's promotion of consumer reviews likewise focuses on the watch's design. *See, e.g.*, Ex. B at 2.

Despite copying Apple Watch's back design, W1's details, materials, and finishes do not

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have the same sophisticated and premium appearance as Apple Watch. Ball ¶ 126–27.

## III. MASIMO INTENDS TO SUBSTANTIALLY EXPAND SALES OF W1 IN THE LATTER HALF OF 2023.

To meet its new need to distribute to consumers for W1, Masimo recently spent \$1.025 billion to acquire subsidiary Sound United, a consumer electronics company with "immediate access to over 20,000 points of retail distribution," including retailers like Best Buy and Amazon, where Apple Watch is sold. Ex. E; Ex. F at 1; Ex. G at 18; Ex. H at 11; Ex. I at 37; Malackowski ¶¶ 59, 67–69. Masimo admits that it is planning to use those distribution channels *in the second half of 2023* for W1 as well as Freedom and B1—forthcoming smart watches that Masimo has suggested will use the same back design as W1. Ex. J at 3; Ex. D at 15; Ex. I at 38; *id.* at 10 (indicating at a recent investor conference that Masimo intends to include the same sensor (*e.g.* the same back of the watch design) as W1 in the forthcoming "Freedom" and "B1" smart watches).

Ex. J at 3.

#### LEGAL STANDARD

The Court may expedite trial and the corresponding discovery schedule in this case pursuant to its broad authority to manage its cases. Fed. R. Civ. P. 16; *see also* D. Del. L.R. 16.1. Rule 16(a) specifically authorizes the Court to convene a conference of the parties "for such purposes as . . . expediting disposition of the action." Fed. R. Civ. P. 16(a)(1). The District of Delaware has previously held that motions to expedite (*e.g.*, in the context of discovery) are governed by a reasonableness standard, under which it is appropriate for the Court to authorize expedited proceedings upon a showing of good cause. *Kone Corp. v. ThyssenKrupp USA, Inc.*, C.A. No. 11-465-LPS-CJB, 2011 WL 4478477, at \*4–6, \*8 (D. Del. Sept. 26, 2011) (finding good cause to expedite limited discovery). Good cause warrants an expedited schedule here.

Courts in this District routinely schedule an expedited trial in the context of injunctive relief where a movant has demonstrated potential harm, even if not irreparable or imminent. For example, in *SecureBuy, LLC v. CardinalCommerce Corporation*, the court denied a declaratory judgment in defendant's motion for preliminary injunction but set an expedited trial within *six months* where the potential irreparable harm could be remedied with an expedited trial. *See* Ex. P (C.A. No. 13-1792-LPS, D.I. 53 (Transcript Of Oral Hearing) at 55-63 (D. Del. Feb. 7, 2014)). That court noted that granting such relief was well within its discretion, and found it was appropriate in that case in view of, among other factors, competition between the parties, potential harm to the movant, and the narrow scope of the case. *Id.* at 62. Other courts in this District have similarly expedited trial on the merits as an alternative to a preliminary injunction. *See, e.g., Cirba Inc. v. VMWARE, Inc.*, C.A. No. 19-742-LPS, 2020 WL 7489765, at \*1 (D. Del. Dec. 21, 2020) ("[T]he Court agreed to hold an expedited trial," to reduce the risk that "VMWARE's alleged infringement would cause Plaintiffs further harm before the case could be decided on the merits,"

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and trial was held *five months* after the preliminary injunction motion denial and *nine months* after the Complaint.); *Eaton Corp. v. Rockwell Int'l Corp.*, C.A. No. 97-421-JJF, 1997 WL 33708214, at \*8 (D. Del. Nov. 4, 1997) (scheduling a trial within *six months* of a denial of a preliminary injunction, which the court found would alleviate plaintiff's hardships, including "to potentially suffer some loss of market share"); *see also Advanced Micro Devices, Inc. v. S3 Graphics Co.*, C.A. No. 11-965-LPS, 2011 WL 5402667, at \*2 (D. Del. Nov. 8, 2011) (noting the "public policy favoring expeditious resolution of disputes" particularly involving patents, and holding that although the requested injunction was not warranted based on irreparable harm, an expedited schedule to resolve the narrow issue for trial was appropriate to accomplish an "expeditious resolution"). Apple brings this motion in lieu of a motion for a preliminary injunction because recent events have revealed that the irreparable harm to Apple caused by Masimo's infringing sales can largely be mitigated by an expedited trial in approximately eight months.

#### **ARGUMENT**

I. AN EXPEDITED TRIAL IS NECESSARY TO MITIGATE IRREPARABLE HARM TO APPLE THAT WILL BE CAUSED BY MASIMO'S PLANNED ESCALATION OF INFRINGING SALES IN THE SECOND HALF OF 2023.

Good cause exists to expedite trial in this case to mitigate the irreparable harm that Apple is likely to sustain in the latter half of 2023 because of Masimo's plans to sell smart watches that copy Apple's iconic patented designs in some of the same retailers that also sell Apple Watch. Apple requests an expedited trial to mitigate those harms by adjudicating Masimo's liability before Masimo's planned expansion so that Apple can seek post-trial injunctive relief, which Apple is likely to successfully obtain.

A. Masimo's Escalating Infringing Sales Will Irreparably Harm Apple In 2023.

Masimo admits that *in the latter half of 2023*, it intends to sell W1 and other smart watches that Masimo has suggested will use W1's infringing design through Sound United's distribution

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channels—including through retailers that sell Apple Watch, like Best Buy and Amazon. Ex. J at 3; Malackowski ¶¶ 67–69, 78. Masimo's competing sales in those retailers will irreparably harm Apple through: (1) unquantifiable lost market share<sup>3</sup> and (2) damage to Apple's reputation. *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344 (Fed. Cir. 2013) ("Irreparable injury encompasses different types of losses that are often difficult to quantify, including lost sales and erosion in reputation[.]"). Those potential harms provide good cause for expediting trial.

# 1. Masimo's Escalating Infringing Sales Will Irreparably Harm Apple By Reducing Apple's Market Share.

It is well established that loss of current or future market share may constitute irreparable harm. See Robert Bosch LLC v. Pylon Mfg. Corp., 659 F.3d 1142, 1152-55 (Fed. Cir. 2011); Apple v. Samsung, 809 F.3d 633, 645-46, 652 (Fed. Cir. 2015) ("Apple IV"). "Where two companies are in competition against one another, the patentee suffers the harm—often irreparable—of being forced to compete against products that incorporate and infringe its own patented inventions." Douglas, 717 F.3d at 1345; Apple IV, 809 F.3d at 646 (infringement "places a substantial hardship" on the plaintiff "by forcing [plaintiff] to compete against its own patented invention") (internal quotations omitted); see also Bosch, 659 F.3d at 1149, 1157 (injunction granted where patentee also practiced patented technology); Trebro Mfg. v. Firefly Equip., 748 F.3d 1159, 1171 (Fed. Cir. 2014) (direct competition "strongly show[ed] a probability for irreparable harm"). In the latter half of 2023, Apple will be forced to do just that: Apple Watch and W1 will be in direct competition at the same retailers, forcing Apple to compete against its own patented inventions. Malackowski ¶¶ 71–86. As Mr. Malackowski, an economics expert, explains, forcing Apple Watch to consumers because

<sup>&</sup>lt;sup>3</sup> As noted above, Apple disputes Masimo's definition of an alleged relevant United States market, but Apple will be irreparably harmed by Masimo's unfair gains in any relevant market.

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consumers (or, their friends) can purchase a similar-in-design product from another source." *Id.* ¶ 89. Thus, "the ready availability of W1 . . . creates a disincentive for consumers to buy the authentic Apple Watch," leading to irreparable losses by Apple. *Id.* ¶ 89.

The harms to Apple from losing market share to Masimo's infringing W1 and Masimo unfairly establishing itself as a new competitor to Apple with the infringing W1 are unquantifiable, and thus irreparable. For example, Masimo's improper foothold in smart watches by virtue of its infringement cannot be addressed by a re-design of W1 upon a finding of infringement because consumer interest in even the re-designed product will be based at least in part on Masimo's prior infringement. Malackowski ¶ 97. Indeed, the Federal Circuit has recognized that "mere damages will not compensate [a patentee] for [] [an accused infringer's] increasing share of the market, a market which [the patentee] competes in, and a market that [the patentee] has in part created with its investment in patented technology." *Douglas Dynamics*, 717 F.3d at 1345; *see also*, *e.g.*, *Bio-Rad Lab'ys*, *Inc.* v. 10X Genomics Inc., 967 F.3d 1353, 1378 (Fed. Cir. 2020) (partially vacating injunctive relief based on balance of hardship factor but finding that irreparable harm was "undeniable"); E.I. DuPont de Nemours & Co. v. Unifrax I LLC, C.A. No. 14-1250-RGA, 2017 WL 4004419, at \*5 (D. Del. Sept. 12, 2017) ("Monetary damages are inadequate . . . because Plaintiff would be forced to compete against a rival gaining market share with Plaintiff's technology."), aff'd, 921 F.3d 1060 (Fed. Cir. 2019).

The potential irreparable harm to Apple described above has a causal nexus to Masimo's infringement at least because the patented designs that Masimo copied from Apple factor into consumers' decisions to buy W1. For example, Masimo heavily features the back design of W1 on its webpage. Malackowski ¶¶ 50, 105. Additionally, survey evidence shows that Masimo's use of the Watch Patents has, at a minimum, "some connection" to the potential lost sales because

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consumers have identified the back design as forming a part of their potential purchasing decisions for W1. *Apple IV*, 809 F.3d at 640 (To prove causal nexus for a patent injunction, the patentee must show "some connection' between the harm alleged and the infringement acts."); Simonson ¶ 33 (36.6% of prospective purchasers familiar with smart watches indicated the design of the back of W1 would impact their purchasing decision); Malackowski ¶ 110.

# 2. Masimo's Escalating Infringing Sales Will Irreparably Harm Apple By Damaging Apple's Reputation.

The Federal Circuit has repeatedly recognized harms to reputation as irreparable. *Douglas*, 717 F.3d at 1344-45. Here, because of Masimo's intentional copying, Masimo's infringement will cause one of two consumer reactions, either of which will irreparably harm Apple's reputation.

First, consumers may mistakenly conclude that Apple's iconic designs are common because they appear on a non-Apple product, resulting in irreparable harm to Apple's reputation as an innovator in design. Through years of investment, Apple has gained a hard-earned reputation for its innovative, design-driven approach. Jue ¶ 4; Malackowski ¶¶ 16–25. Apple's iconic designs, including in Apple Watch, form a key part of Apple's brand identity—a central focus within Apple, as well as for consumers. Jue ¶ 4; Russell-Clark ¶¶ 4–6; Malackowski ¶¶ 22–24, 115. But knock-offs like W1 irreparably harm Apple's reputation for innovation and damage the brand value that those designs provide. Malackowski ¶¶ 115–21. If consumers can purchase almost the same-looking design from another source, they may conclude, incorrectly, that Apple's designs are no longer innovative. Malackowski ¶ 116; Douglas, 717 F.3d at 1344–45 ("Douglas's reputation as an innovator will certainly be damaged if customers found the same 'innovations' appearing in competitors' snowplows, particularly products considered less prestigious and innovative."); see also Tinnus Enters., LLC v. Telebrands Corp., 846 F.3d 1190, 1208 (Fed. Cir. 2017) (finding irreparable harm where infringement "establishes persisting harm to [plaintiff]'s

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reputation and tarnishes its status as the innovator"); *Apple IV*, 809 F.3d at 654 (Reyna, J., concurring) ("The presence of the patented features in [accused] products . . . communicates . . . that Apple's corresponding features are commonplace, not innovative," so infringement "neutralizes the beneficial impact that Apple's corresponding features have in the mind of the consumer."); *see also id.* at 652–56. That harm exists even if a consumer knowingly chooses a less innovative infringing product. *Douglas*, 717 F.3d at 1344–45.

**Second**, Masimo's infringement risks irreparably harming Apple's reputation as a provider of high-quality products because consumers are likely to associate Apple with W1, which is an inferior product over which Apple has no control. Apple Watch uses high-quality materials, and its finishes are highly sophisticated, rivaling what a consumer would expect from a piece of jewelry. Ball ¶ 126. But W1's details, materials, and finishes do not have the same sophisticated and premium appearance. Id. ¶ 127. Masimo's copying of Apple's patented designs will cause consumers to mistakenly believe that Apple is somehow involved with W1. Malackowski ¶ 123; Simonson ¶ 45. Indeed, recent surveys demonstrate that the public is likely to associate the design of the back of W1 with Apple. *Id.* ¶¶ 45, 47 (finding that up to 50% of prospective smart watch purchasers associate the design of the back of W1 with Apple, relative to approximately 10% of respondents who associate a control with Apple). That mistaken consumer belief will irreparably harm Apple by signaling that it is departing from its reputation for producing only high-quality products. Malackowski ¶¶ 122–26; CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc., 893 F. Supp. 508, 524 (D. Md. 1995), aff'd, 92 F.3d 1203 (Fed. Cir. 1996) (finding sales of accused product in the discount trade would diminish the patentee's cultivated high-quality image); see also, e.g., Clamp-Swing Pricing Co. v. Super Mkt. Merch. & Supply, Inc., No. 13-cv-04515-WHO, 2013 U.S. Dist. LEXIS 166638, at \*17 (N.D. Cal. Nov. 21, 2013) (finding irreparable harm from

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"[i]nferior quality" product in trade dress case); *Douglas*, 717 F.3d at 1344–45. That harm to Apple's reputation cannot be quantified and is thus irreparable. Malackowski ¶¶ 125–26.

The irreparable harms to Apple's reputation have a causal nexus to Masimo's infringement because each is caused by Masimo's use of Apple's patented designs in W1. For example, Dr. Simonson's surveys provide direct evidence that the public is likely to associate Apple with W1 *because* of the back design. Simonson ¶¶ 45, 47; Malackowski ¶ 125.

# B. An Expedited Trial Would Mitigate Irreparable Harm To Apple Because Apple Is Likely To Prevail At Trial And Obtain Post-Trial Injunctive Relief.

An expedited trial on liability is warranted because it would expedite Apple's anticipated request for post-trial injunctive relief, which, if obtained, would mitigate the irreparable harms likely to escalate in the latter half of 2023 as described above. In order to obtain post-trial injunctive relief, Apple will need to prove infringement of at least one valid claim at trial as well as each of the following requirements for injunctive relief: (1) that it has suffered an irreparable injury; (2) that remedies available at law are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). Apple is likely to do so here. Thus, good cause exists for expediting trial to mitigate the irreparable harms likely to escalate this year.

#### 1. Apple Is Likely To Succeed On The Merits At An Expedited Trial.

#### a. Masimo Likely Infringes The Watch Patents.

Apple is likely to prove at trial that Masimo's W1 watch infringes at least the Watch Patents.<sup>4</sup> An accused product infringes a claimed design if the two are "substantially similar."

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<sup>&</sup>lt;sup>4</sup> Masimo also likely infringes the asserted charger Patent, but the focus of this Motion is Masimo's likely infringement of the Watch Patents.

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in-Suit. *BlephEx*, 24 F.4th at 1399. Apple is not aware of any such prior art. As Mr. Ball explains, the claimed ornamental features depart notably and conspicuously from the prior art cited during prosecution. Ball ¶¶ 129, 141–47, 166–69, 189–92. Further, Masimo is also unlikely to overcome the evidence of the patented designs' commercial success, industry praise, and copying—objective factors that negate obviousness. Malackowski ¶¶ 145–52; *see Campbell Soup Co. v. Gamon Plus, Inc.*, 10 F.4th 1268, 1278 (Fed. Cir. 2021).

Masimo is likewise unlikely to succeed if it argues that the claimed designs are "primarily functional" or compelled by function. Ball ¶¶ 205–11, 214–19, 222–27; *see Auto. Body Parts Ass'n v. Ford Glo. Techs., LLC*, 930 F.3d 1314, 1320 (Fed. Cir. 2019). The availability of many designs for the rear of watches with similar functionality that, unlike W1, do not use the claimed designs belies any such argument. *See, e.g.*, Ball ¶¶ 207–11; *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1378 (Fed. Cir. 2002) ("[I]f other designs could produce the same or similar functional capabilities, the design of the article in question is likely ornamental, not functional."). Indeed, Apple Watch's rear design as claimed in the patents was not dictated by functionality. Russell-Clark ¶¶ 10–12; Ball ¶¶ 205–11, 214–19, 222–27.<sup>5</sup>

## 2. Apple Is Likely To Prove The Other Necessary Factors For A Permanent Injunction.

Once successful at a trial on the merits, Apple is likely to demonstrate the requirements to obtain post-trial injunctive relief. As described in Section I.A, Apple is likely to prove: (1) that it has suffered an irreparable injury and (2) that remedies available at law are inadequate to compensate for that injury. Additionally, Apple is likely to show: (3) that considering the balance

<sup>&</sup>lt;sup>5</sup> Masimo is also unlikely to prove that the Patents-in-Suit are unenforceable due to inequitable conduct. Masimo's allegations of inequitable conduct—that Apple (1) withheld its own utility patents that allegedly show that the patented designs are functional; and (2) failed to name as inventors on the Patents-in-Suit, inventors who are listed on those Apple utility patents—are both premised on the incorrect assertion that the designs in the Patents-in-Suit are dictated by function.

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of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

The balance of hardships tips sharply in Apple's favor. Masimo will suffer minimal hardship if sales of W1 are enjoined. W1 is indisputably not a core product of Masimo—its core business is hospital devices, which are not implicated in this case. Malackowski ¶¶ 46, 48, 142; i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 862–63 (Fed. Cir. 2010). And Apple seeks an expedited trial precisely to resolve this dispute before W1 receives widespread adoption or entrenchment in the market. See Trebro, 748 F.3d at 1171 (balance of equities favored patentee, who was "losing business to a new entrant"); Shibumi Shade, Inc. v. Beach Shade LLC, No. 5:21cv-256, 2022 WL 390839, at \*17 (E.D.N.C. Feb. 8, 2022) (balance of equities favored injunction because "plaintiff acted quickly . . . to return to status quo ante once defendants changed the state of affairs by offering a likely infringing product not previously on the market"). Further, the Court should discount any harm to Masimo because Masimo itself elected to infringe. See Bosch, 659 F.3d at 1156 (citing Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 n. 12 (Fed. Cir. 1986) ("One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected."); Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 931 (Fed. Cir. 2012) (defendant's "losses were the result of its own calculated risk in selling a product with knowledge of [plaintiff's] patent").

Apple is also likely to show that the public interest favors injunctive relief. First, an injunction of W1 would be narrowly tailored to an infringing, non-clinical consumer product that does not have widespread utilization or adoption and for which substitutes are available, including from Apple. *See i4i*, 598 F.3d at 863. Second, there is a strong public policy interest in the enforcement of patent rights. *See Celsis*, 664 F.3d at 931. Although competition serves the public

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interest, "cheap copies of patented inventions," like W1, "have the effect of inhibiting innovation and incentive," which harms the public, favoring an injunction. *Douglas*, 717 F.3d at 1346.

#### II. EXPEDITING TRIAL WOULD NOT UNDULY PREJUDICE MASIMO.

Given the narrow scope of discovery and pre-trial proceedings necessary to resolve liability in this case, discussed in detail in Section III below, proceeding on an expedited schedule will not prejudice Masimo. In fact, both Apple and Masimo will benefit from resolving this dispute expeditiously. *Takeda Pharm. Co. Ltd. v. Norwich Pharms., Inc.*, No. 20-cv-8966-SRC, 2022 WL 2759961, at \*3 (D.N.J. July 14, 2022) (finding that an expedited schedule did not unduly prejudice either party, and, in fact, "[t]he benefit that results from working toward earlier deadlines is a speedier resolution of the dispute, which benefits both parties").

Indeed, an expeditious trial in this case will benefit Masimo by providing certainty as to Apple's claims of infringement before Masimo expends further resources in significantly expanding its manufacturing and distribution infrastructure for W1, which it plans to do in the latter half of 2023. Masimo has also suggested that it intends to include the same back design included in W1 in at least two more watches, Freedom and B1, which it intends to launch through Sound United's distribution channels in the second half of 2023. Ex. J at 3; Ex. I at 10, 17, 38. A prompt final adjudication of the pending infringement claims will also allow Masimo to make any necessary changes to those planned future products before they are released.

## III. AN EXPEDITED TRIAL IS WARRANTED BASED ON THE NARROW SCOPE OF THE ISSUES FOR TRIAL.

An expedited trial to adjudicate Masimo's willful infringement of Apple's design patents is appropriate given the narrow scope of the issues for discovery and trial. In a recent case before this Court involving only design patents, trial was set within ten months of the scheduling order even without a motion for expedited trial demonstrating irreparable harm. Ex. Q (*Gavrieli Brands* 

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Respectfully submitted,

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# **EXHIBIT 35**

#### Kendall Loebbaka

**From:** Frazier, Sarah <Sarah.Frazier@wilmerhale.com>

Sent: Thursday, December 28, 2023 10:00 AM

To: Kendall Loebbaka; WH Apple-Masimo ITC Team

Cc: Masimo.AppleITC

**Subject:** RE: ITC No 337-TA-1276 | Redactions to Commission Order

Kendall,

The order itself was not confidential. Apple does not have any redactions to the Commission's Opinion.

Thanks, Sarah

From: Kendall Loebbaka < Kendall Loebbaka@knobbe.com>

Sent: Thursday, December 21, 2023 12:52 PM

To: WH Apple-Masimo ITC Team < WHApple-Masimo ITC Team@wilmerhale.com>

Cc: Masimo.AppleITC < Masimo.AppleITC@knobbe.com >

Subject: ITC No 337-TA-1276 | Redactions to Commission Order

#### **EXTERNAL SENDER**

#### Counsel,

Masimo does not have any redactions to the Commission's December 20 order denying Apple's motion to stay. In view of the holidays, please provide by the close of business tomorrow, December 22, Apple's proposed redactions or confirm that Apple does not have any redactions.

Best regards, Kendall

#### Kendall Loebbaka

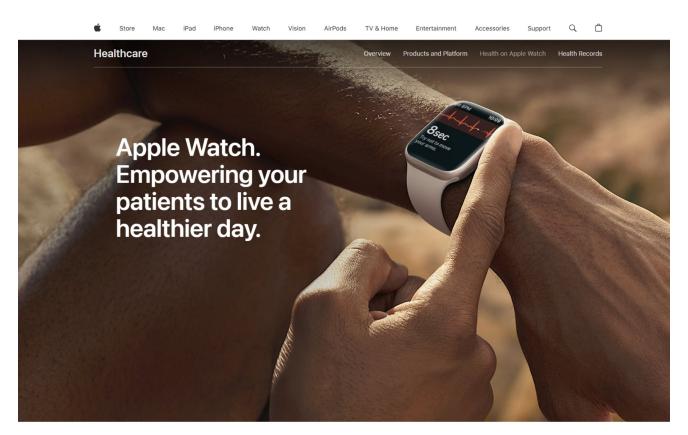
Partner

949-721-7687 Direct

**Knobbe Martens** 

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# **EXHIBIT 36**



Apple Watch has powerful apps that make it the ultimate device for a healthy life. And it can support you and your patients across multiple aspects of health including heart health, mobility, activity, medications, and more.

# Heart rate notifications.

01/04/2024

Apple Watch checks for unusually high or low heart rates in the background, which could be signs of a serious underlying condition. This could help you and your patients identify situations that may warrant further evaluation.

If a patient's heart rate is above 120 bpm or below 40 bpm while they appear to have been inactive for 10 minutes, the user will receive a notification. Patients can adjust the threshold bpm or turn these notifications on or off. All heart rate notifications — along with date, time, and heart rate — can be viewed in the Health app on iPhone.

Learn more about heart rate notifications >



01/04/2024



# Irregular rhythm notifications.

The irregular rhythm notification occasionally checks for signs of irregular rhythms that may be suggestive of atrial fibrillation (AFib). This feature won't detect all instances of AFib, but may catch something that can provide your patients with an early indication that further evaluation may be warranted.

Irregular rhythm notifications use the optical heart sensor to detect the pulse wave at the wrist and look for variability in beat-to-beat intervals when the user is at rest. If the algorithm repeatedly detects an irregular rhythm suggestive of AFib, your patient will receive a notification and the date, time, and beat-to-beat heart rate will be recorded in the Health app.

In a clinical study using an FDA-cleared patch ECG as a reference device, the irregular rhythm notification feature demonstrated a sensitivity of 88.6% and a detection specificity of 99.3%.

The irregular rhythm notification feature received 510(k) clearance from the FDA for users 22 years and older with no prior history of AFib.

Learn more about irregular rhythm notifications >

#### ECG app.

With the ECG app, patients who experience symptoms such as rapid or skipped heartbeat, or receive the irregular rhythm notification, can capture an ECG and record their symptoms. This real-world data can enable you to make more informed and timely decisions regarding further evaluation and care.

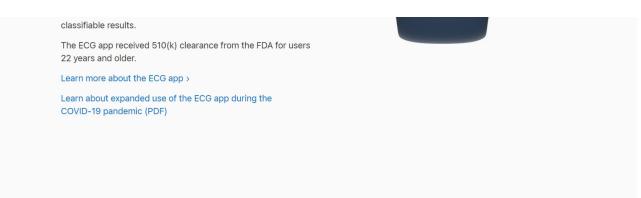
The ECG app uses the electrical heart sensor built into the Digital Crown and the back crystal to record a single-lead ECG similar to a Lead I ECG. The ECG app then provides a result of sinus rhythm, atrial fibrillation, atrial fibrillation with high heart rate, inconclusive, or poor recording, and prompts the user to enter any symptoms such as rapid or pounding heartbeat, dizziness, or fatigue. An inconclusive result may occur if there is presence of arrhythmias other than AFib, presence of an ICD or pacemaker, or poor electrical signal, which can result from right axis deviation. The recorded waveform, results, date, time, and any symptoms are recorded and can be exported from the Health app as a PDF to share with a clinician. If the patient notes symptoms that indicate a serious condition, they are prompted to immediately call emergency services.

In a clinical study using a 12-lead ECG as a reference device, the ECG app demonstrated 99.3% specificity in classifying sinus rhythm and 98.5% sensitivity in classifying AFib for the



https://www.apple.com/healthcare/apple-watch/

01/04/2024

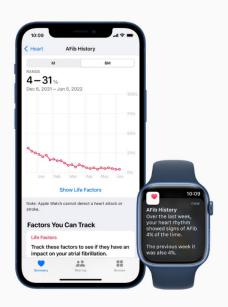


#### How the ECG app works.



1. Launch the ECG app on Apple Watch Series 4 or later.\*

. . . . .



#### AFib History.

AFib History is a first-of-its-kind feature that provides patients who are diagnosed with atrial fibrillation with lifestyle insights and long-term tracking of how frequently they show signs of AFib. Your patients will receive notifications with an estimate of the time they spent in AFib each week while wearing their Apple Watch. Patients can also view a detailed history in the

Your patients can also track lifestyle factors that may contribute to their condition, including weight, exercise, sleep, alcohol consumption, and mindful minutes. These factors are charted alongside their AFib burden to help them better understand the relationship between their lifestyle and AFib.

AFib History is FDA cleared for users 22 years and older with a diagnosis of atrial fibrillation. Once AFib History is turned on, irregular rhythm notifications will be automatically turned off.

3 of 7

#### Validation of AFib detection and monitoring features.

Each feature on Apple Watch is subject to rigorous scientific validation to help your patients receive trustworthy and reliable insights. In 2017 and 2018, researchers at Stanford University School of Medicine worked with Apple on the Apple Heart Study and over 400,000 Apple Watch users to validate the ability of wearable technology to aid in the early detection of atrial fibrillation and to support the introduction of the irregular rhythm notification feature. Since then Apple has conducted several prospective multicenter clinical trials to support additional products, including the ECG app, enhancements to the irregular rhythm notification feature, and most recently, the AFib History feature.

See the results of the Apple Heart Study  $\Brightarrow$ 

Case: 24-1285

Learn more about arrhythmia detection validation (PDF)

"Products that seek to provide deeper health insights, like the Apple Watch, have the potential to be significant in new clinical care models and shared decision making between people and their healthcare providers."

> **Dr. Ivor Benjamin** Immediate Past President of the American Heart Association

> > . .

#### Compare Apple Watch models.

	Heart Rate and Irregular Rhythm Notifications	AFib History	ECG App	Low Cardio Fitness Notifications	Blood Oxygen Level	Fall Detection
Sensors	Optical heart sensor	Optical heart sensor	Electrical heart sensor	Optical heart sensor and GPS	Optical heart sensor	Accelerometer and gyroscope
Apple Watch Series 3	•	8	8	•	8	8
Apple Watch SE	•	•	8	•	8	•
Apple Watch Series 4 and 5	•	<b>Ø</b>	<b>Ø</b>	•	8	•
Apple Watch Series 6 or later	•	•	•	•	•	<b>Ø</b>
Apple Watch Ultra	•	•	•	•	•	<b>Ø</b>

# Mobility and Cardio Fitness.

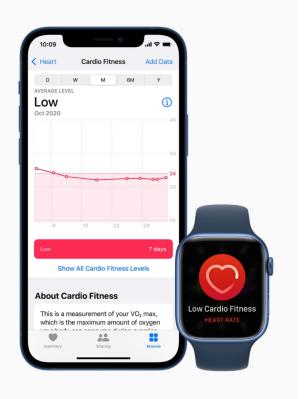
Mobility and cardiovascular fitness can be strong indicators of overall physical health and a predictor of long-term well-being. Apple Watch and iPhone can provide estimates of mobility metrics to give you and your patients a better understanding of how they impact mobility today and provide tools to monitor these factors over time. Mobility metrics include Cardio Fitness (VO $_2$  max), Six-Minute Walk Distance, and other metrics used to measure walking quality (Walking Speed, Step Length, Double Support Time, and Walking Asymmetry). These metrics can be utilized for research and app development with the user's permission.

Learn more about how these metrics were developed and validated:

Using Apple Watch to Estimate Cardio Fitness with VO<sub>2</sub> max (PDF)

Using Apple Watch to Estimate Six-Minute Walk Distance (PDF)

Measuring Walking Quality Through iPhone Mobility Metrics (PDF)





#### Fall detection.

When a hard fall is detected with Apple Watch Series 4 or later, an alert appears and allows the user to easily call emergency services or dismiss the alert. If the user is unresponsive for about a minute, an emergency call will be placed automatically and a message will be sent to the user's emergency contacts. All falls detected are recorded in the Health app. This feature is automatically enabled for users 55 years and older and can be turned on for anyone in the Apple Watch app on iPhone.

Learn more about fall detection >

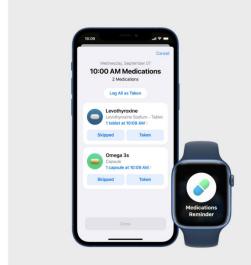
Medical ID.

Medical ID allows fire

Medical ID allows first responders and emergency room clinicians to access critical medical information from a patient's iPhone Lock Screen or Apple Watch without requiring a passcode and without compromising patient privacy. Patients can list important information such as allergies, medications, conditions, organ donor preferences, and emergency contacts by setting up Medical ID in the Health app on iBhane.

Learn more about accessing Medical ID on Apple Watch >





#### Medications.

The Medications experience on iPhone and Apple Watch helps your patients track and manage the medications they take. Your patients can receive reminders to log scheduled medications, see medication adherence over time, and review their active medications list.

# Facilitate richer conversations.

The Health app on iPhone makes it easier than ever for your patients to visualize and securely store their health records from multiple institutions alongside their patient-generated data, creating a more holistic view of their health. Patients can now share their Health app data, which you can view within your EHR workflow.

Learn more about health records on iPhone >

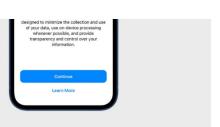




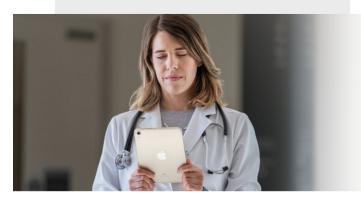
# Designed with security and privacy in mind.

When a user's iPhone is locked with a passcode, Touch ID, or Face ID, their health data in the Health app is encrypted

https://www.apple.com/healthcare/apple-watch/



on the device. If a user chooses to sync their health data with iCloud, it is encrypted while in transit and at rest.



01/04/2024

# The future of healthcare is in your hands.

Learn more about Apple in Healthcare >







# And the future of health is on your wrist.

Learn more about Apple Watch >

\* ECG app not supported on Apple Watch SE 🔹 > Healthcare > Health on Apple Watch Apple Store For Business Apple Values Store Manage Your Apple ID Find a Store Apple and Business Accessibility Mac Apple Store Account Genius Bar Shop for Business Education iPad iCloud.com Today at Apple Environment For Education Inclusion and Diversity Apple Camp iPhone Entertainment Apple and Education Watch Apple Store App Privacy Apple One Shop for K-12 Certified Refurbished Racial Equity and Justice Shop for College Apple TV+ Apple Trade In Supplier Responsibility Apple Music Financing For Healthcare Apple Arcade About Apple AirTag Carrier Deals at Apple Apple in Healthcare Apple Fitness+ Order Status Accessories Health on Apple Watch Apple News+ Apple Leadership Shopping Help Gift Cards Health Records on iPhone Apple Podcasts Career Opportunities Apple Wallet Apple Books Investors Wallet App Store Ethics & Compliance Shop for Government Apple Card Events Shop for Veterans and Military Apple Pay Contact Apple Apple Cash More ways to shop: Find an Apple Store or other retailer near you. Or call 1-800-MY-APPLE. Copyright © 2024 Apple Inc. All rights reserved. Privacy Policy | Terms of Use | Sales and Refunds | Legal | Site Map United States

MAS-ADD-461

7 of 7

# **EXHIBIT 37**

Subject: Re: Marcelo Lamego

From: "James Foster" <jhfoster@apple.com>
Received(Date): Tue, 22 Jan 2013 04:31:03 +0000

To: "David Affourtit" <affourtit@apple.com>

Date: Tue, 22 Jan 2013 04:31:03 +0000

Liked him allot and want to get him up BUT we need to get an NDA with this chap.

He commented that as an officer of Cercacor he is unable to sign an NDA can you verify with legal.

Thanks

James.

On Jan 21, 2013, at 4:39 PM, David Affourtit <affourtit@apple.com> wrote:

> Hello James.

>

- > You're scheduled to call Marcelo this eve (7:30pm). I felt this guys passion and drive. It was quite infectious. Very hands on, into the details, a doer with what felt like natural leadership chops. Very interesting projects, but lacks the MD or a Biomedical degrees. PhD EE Stanford with heavy slant towards bio. Trying to determine if he picked up enough of the science in industry to help as a med lead, but like Imad Libbus, maybe there is a different role, etc.
- > Cercacor was basically spun out of Masimo. They shipped Pronto7 and are working on subsequent versions, etc. They spun out, as he puts it: "mainly to remove the work from the big company culture evolving within Masimo at large"). Marcelo & Joe Kiani, CEO Masimo, are the two sole officers of Cercacor Labs. This guy Joe has a "Steve Jobs" like reputation within the space. I've heard Marcelo is one of Joe's key guys.

> Here is a link to a patent application filed by Cercacor Labs named: "Pediatric Monitor Sensor Steady Game" http://www.freepatentsonline.com/y2012/0283524.html

> Here is a gov. doc describing how Cercacor Labs, Inc. is set up. http://www.sec.gov/Archives/edgar/data/937556/000119312512447065/R8.htm

> Marcelo isn't active. He sees the likelihood of unhooking from Joe & Cercacor low. BUT, he admits, the possibilities with a real Apple committment to this domain would be enormous. So with that, he's anxious to engage and learn more.

> One thing to note. His biggest anxiety would be his personal dislike for large company cultures. He felt Masimo was getting too big at 2k... So, I explained how Apple is more nimble & "flat" compared to your typical companies...

Masimo Corp. v. Apple Inc.

JTX 648

Case No. 8:20-cv-00048-JVS-JDE

Sellers Exhibit 3402 (12-15-21)

- > Anxious to learn your impressions after the call.
- >
- > Thanks,
- > Dave
- >
- > <Marcelo\_Lamego.pdf>

# **EXHIBIT 38**

Subject: Fwd: Key Technologies tracking

From: "Steve Hotelling" <shotelling@apple.com>

Received(Date): Thu, 30 May 2013 17:25:50 +0000

To: "Heidi Delgado" <hdelgado@apple.com>

Attachment: Rover\_0227.key

Date: Thu, 30 May 2013 17:25:50 +0000

Rover example as template

Begin forwarded message:



Masimo Corp. v. Apple Inc.

JTX 260

Case No. 8:20-cv-00048-JVS-JDE

Hotelling Exhibit 260 (8-2-22)

APL-MAS\_00909102



APL-MAS\_00909103



Exhibit L Page 4

APL-MAS\_00909105

Angle Conficientia

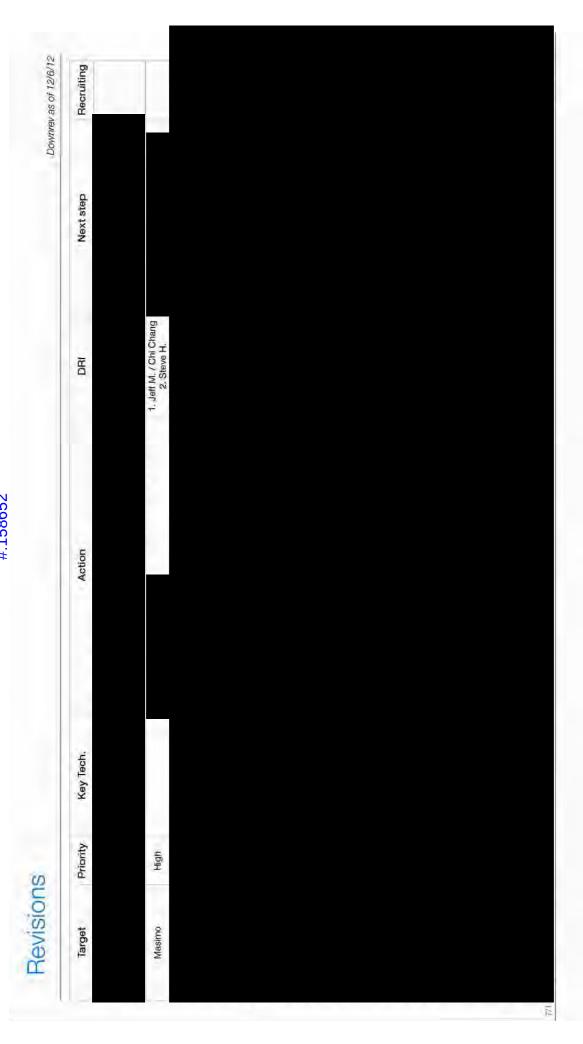
# PPG Development Partner | Sensing Goals

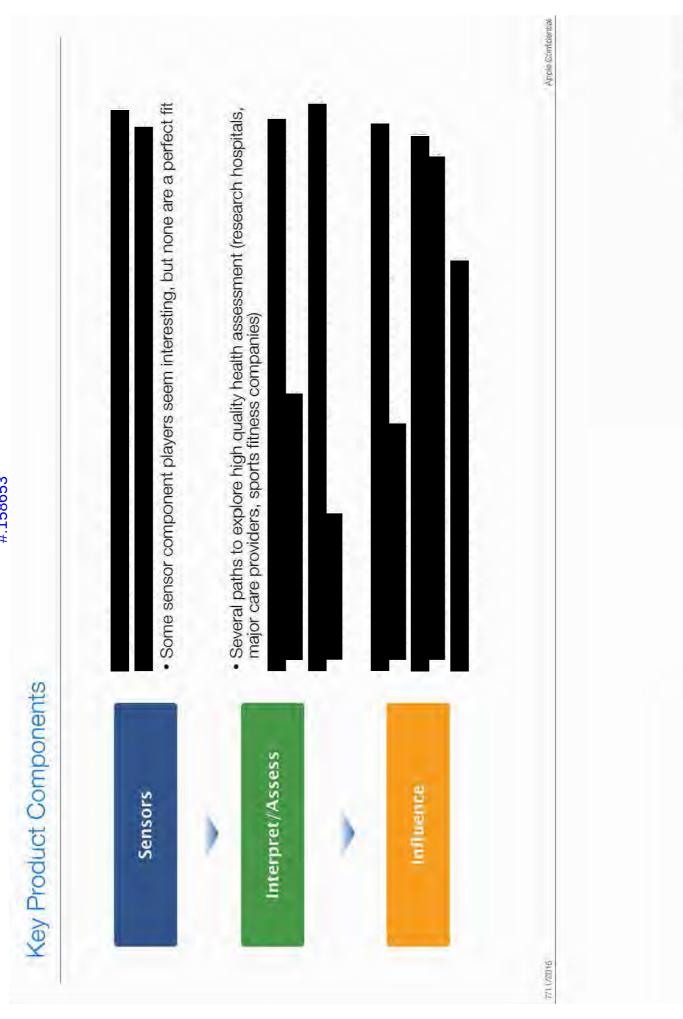
Identify a team of world experts who have years of experience designing and shipping PPG sensors

processing options. Have a good sense for which sensor fusion ideas are likely to work, and which ones have been - Have "been there, done that" with the myriad approaches for optical configurations, analog approaches, signal tried and failed (and they know why they failed)

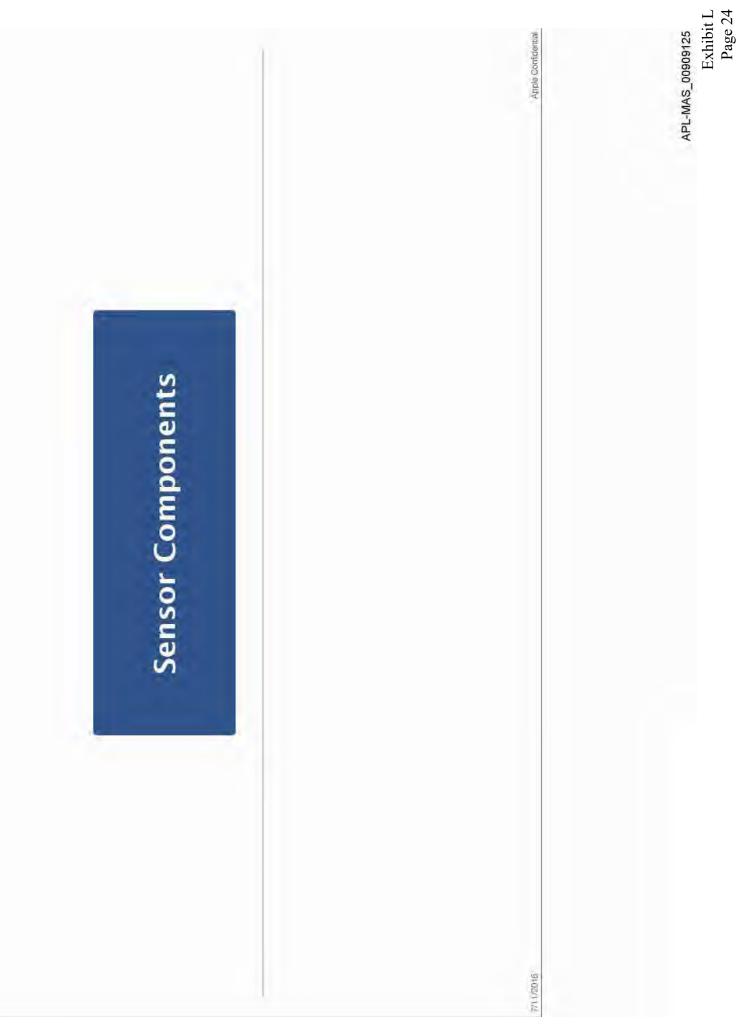
- Create the "worlds best" wrist PPG by combining the best attributes of both teams.
- Similar to Authentec/Apple collaboration model.
- 3rd party experienced team teaches Apple team all of the existing and near-term planned technology, and the key factors limiting performance.
- Apple uses this stepping stone to innovate the "worlds best" and quickly brings it to market.

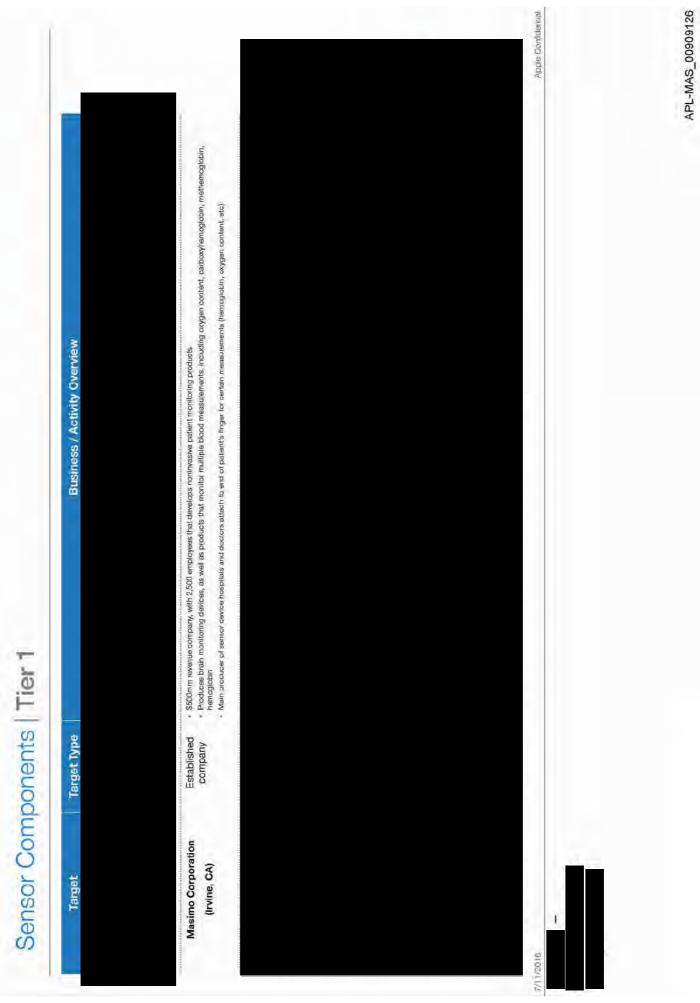
2/11/2016





# Sensor Devices | Tier 2





# Sensor Components | Tier 2

Subject: Re: Masimo - PRIVILEGED AND CONFIDENTIAL

From: "James Foster" < jhfoster@apple.com>

Received(Date): Tue, 14 May 2013 22:31:31 +0000

To: "Adrian Perica" <perica@apple.com>
Date: Tue, 14 May 2013 22:31:31 +0000

### Adrian,

I discussed Massimo with Bob today, reinforcing how much we liked both their technology, leadership and position.

Bob asked why don't we just buy them.

Lets chat this one through, clearly some issues but there are a few good reasons for doing it.

James.

On May 5, 2013, at 9:33 PM, Adrian Perica <perica@apple.com> wrote:

> PRIVILEGED AND CONFIDENTIAL

>

> Bob.

>

- > On Friday afternoon, we had a very interesting meeting with the CEO of Masmio, Joe Kiani, and his VP of Marketing and Clinical Development but we need to make some strategic decisions.
- > Masimo leads the industry in PPGs that can handle motion and is expanding to other non-invasive optical measurements. Their near-term push is on hemoglobin. They have an active effort in glucose. Joe even mentioned in his opening remarks that when we started the business 20 years ago, glucose was on his mind.
- > Joe is an electrical engineer by training and was going through equations on the board with us. Solid guy.
- > We need to make strategic decisions for a few reasons:
- > 1. Joe was wondering our intentions in this space. He's heard we are hiring spectroscopy experts and that we were looking at C8 Medisensors (the bankrupt glucose company that Michael Hillman was investigating)
- > 2. We are actively talking to his EVP of Medical Affairs, Dr. Mike O'Reilly.
- > 3. There are ways Apple and Masimo might work together on tech development for N38





> 4. There are definitely ways Apple and Masimo can work together in the Healthcare ecosystem to jointly market products, Apple feature their products, Masimo work to put iOS at the center of their new platform and help Apple defined an interface spec.

> Joe was pretty forthcoming with us on Friday but he's clearly apprehensive sharing too much with us about their consumer plans. He openly said he planned on sharing more but got a little concerned about our spectroscopy efforts.

> We'll find time on your calendar to discuss after the team has a recommendation.

> Thanks,

> Adrian

>

>

Case: 24-1285 Document: 25-3 Page: 404 Filed: 01/10/2024

Subject: Re: Masimo Sensitivity

From: "Adrian Perica" <perica@apple.com> Received(Date): Thu, 27 Jun 2013 23:38:43 +0000

> To: "Peter Oppenheimer" < oppenheimer@apple.com> Cc: "Robert Mansfield" <mansfield@apple.com>

Date: Thu, 27 Jun 2013 23:38:43 +0000

Yes, that's for the future Rainbow tech, which potentially collects many signals beyond blood oxygenation and pulse that the current finger leads do in hospitals. The company is called Cercacor and is actually consolidated on Masimo's B/S based on the related party nature of the ownership and the beneficial nature of the licenses flowing back and forth.

Joe told us that he split them because the VCs didn't see the potential value of glucose and other blood measurements back when he was raising capital, so he wanted to keep it out of the funding.

I've actually thought that Joe could be the VP of Medical Technologies at Apple and that we could have bought the whole company to kick this off. He's a electrical engineer by training but has built a medical business as the scrappy underdog vs. Tyco/Nellcor in this space and his company has lots of ideas regarding non-invasive monitoring.

Masimo is \$1.2B market cap and \$500mm in revs with \$60mm of FCF.... We should buy the company for the cash flow or one person but it would be a big step into the professional medical monitoring space vs. the consumer stuff we're targeting now. Instant credibility in that world with knowledge of the FDA trials, what's going on at hospitals, sales teams, etc.

Thanks. Adrian

On Jun 27, 2013, at 4:30 PM, Peter Oppenheimer <a href="mailto:oppenheimer@apple.com">oppenheimer@apple.com</a> wrote:

> When I met with Mike, he told me that the IP sits in a private company that the CEO and others own. Masimo has a license to the technology with certain limits. He said the CEO did this to insulate the technology from takeover attempts of the public company.

> On Jun 27, 2013, at 4:25 PM, Adrian Perica <perica@apple.com> wrote:

>>

>> Bob/Peter,

>> I wanted to check-in re: Mike O'Reilly and Masimo to see if we need to make Tim aware in case the CEO, Joe Kiani, gets animated. Sounds like Mike is going to tell Joe





on Monday about leaving to join Apple.

>>

>> As background, a group of us met with Joe on May 3rd when he flew up here with his VP, Marketing to discuss potential ways the companies can work together. We reached out to Masimo to potentially collaborate on the PPG light sensor going into N27. Apple started talking to Mike before we reached out formally for N27 support. Joe doesn't yet know of N27 but he was skittish in our original meeting because his industry contacts picked up that Apple has been hiring spectroscopy experts.

>> Nothing specifically came out the meeting except that the two companies should continue getting to know each other. To that end, Ron Hernandez is in the process of setting up a meeting between Joe, Bob and me. It was supposed to be this week but got pushed for schedules. Conceptually, we were going to continue exploring ways to work together and maybe even touch on M&A. I have tentative holds on my calendar for July 17th and 18th.

>>

>> Mike is listed on their website as part of Masimo's executive team.

>>

>> Not sure anything negative will happen but I wanted to flag it.

>>

>> Thanks,

>> Adrian

>>

>> http://www.masimo.com/aboutmasimo/keypersonnel.htm

>>

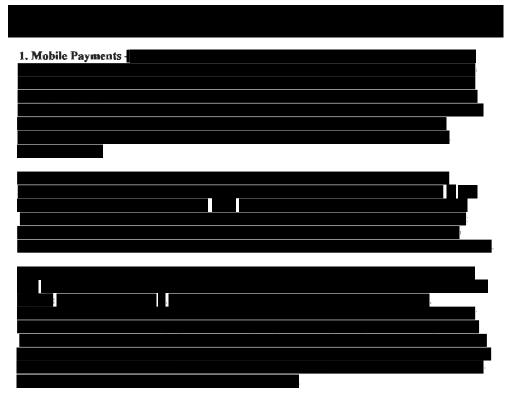
>> >>

>

Subject: Re: M&A

From: "Adrian Perica" <perica@apple.com>
Received(Date): Wed, 03 Jul 2013 22:31:22 +0000
To: "Tim Cook" <tcook@apple.com>

Date: Wed, 03 Jul 2013 22:31:22 +0000



- 2. Wellness/Medical Whereas I feel like the payments pool of leaders is thin, I think lots of people in and around healthcare knows what needs to be done. They just don't know how to do it or have the power to do it. We have the beginnings of leaders in the three areas below but no one yet to pull it all together:
- Coaching/Wellness To me, this is the very emotional part of getting motivated and staying motivated. I think Jay Blahnik working with Kevin to nail N27 is a great start
- Cloud/Ecosytem fostering Everyone knows the world is clamoring for a medical cloud, but we aren't doing anything about it fast enough. Kevin is building one for N27 that is extensible,





Case 8:20-cv-00048-JVS-JDE Document 1801-18 Filed 06/26/23 Page 3 of 6 Page ID #:154100

but that's not thinking big enough and he's got N27 to deliver. I think Mike O'Reilly can help but we really need a leader who understands the space better and more resources to build a real cloud that unleashes our app model for medical data. Plus, we need lots of focus to work with a few partners to make the cloud an early success with major players.

- Non-invasive diagnostics - In some ways, we're the most clueless here but on the other hand, we internally understand how to be good at these engineering disciplines.

Thus, the Medical leader we need to pull it all together and it's not Mike O'Reilly. I'm personally a little surprised we made him a VP of Medical Technologies. I love Mike and want him to join to contribute in many areas, but I thought he'd be a Senior Director. He's a leader of sorts but he's really a staff person and continues to be a practicing anesthesiologist. If Mike Culbert were alive, I think Mike O'Reilly would have reported to him. That org fit makes sense to me.

I was actually thinking that the founder and CEO of Masimo, Joe Kiani, is a great example of a VP of Medical Technologies at Apple. This is not a recruiting alternative, but I had talked with Bob about going down to meet Joe in Irvine and potentially exploring an acquisition of Masimo. It's got a \$1.2B market cap and is major player in hospital pulse-ox with \$500mm in revs. They want to expand in other non-invasive patient diagnostics both in the hospital and potentially outside. Masimo also happens to be working on non-invasive glucose monitoring and Joe started a foundation to promote "Ethics, Innovation, and Competition in Healthcare". He's an Electrical Engineering by training and we met him as part of learning if we could partner on the PPG sensor. Acquisitions of this size aren't our style but I think we need someone like Joe who has been successfully working with global hospitals and medical people every day for the past 15 years to drive the overarching wellness/medical efforts at Apple, which is bigger than any one product. Importantly, Joe and Masimo are something like outsiders in medicine compared to the pulse-ox incumbent Covidien (Tyco Healthcare) and the massive medical device, capital goods, and pharma companies.

http://www.masimo.com/aboutmasimo/evolution.htm

http://www.masimofoundation.com

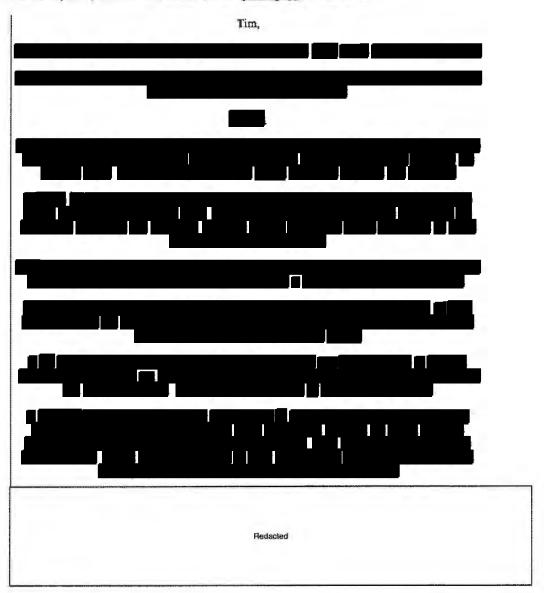
Thanks,

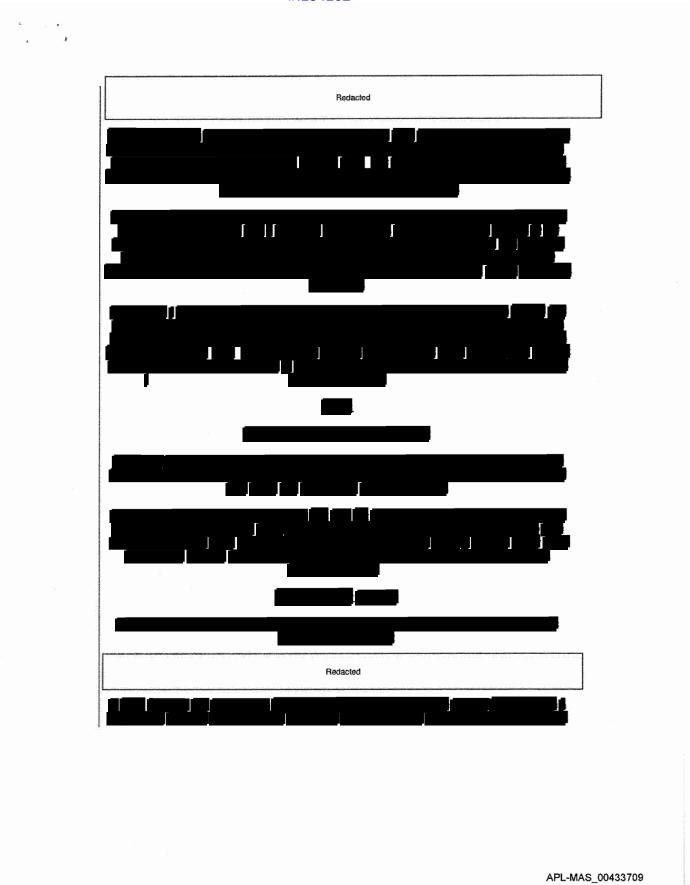
Adrian

Redacted

Redacted

On Jun 29, 2013, at 11:36 AM, Adrian Perica operica@apple.com> wrote:





\*...



Thanks,

Adrian

<3Q13YTD Acquisition Summary.pdf>

On Jun 29, 2013, at 9:45 AM, Tim Cook < tcook@apple.com > wrote:

Adrian,

Please send me a list of acquisitions closed though the first three quarters of the fiscal year along with the \$ amounts and brief description. How many are in the pipeline?

Tim

### 

Subject: Re: Rover | 8/28

From: "Adrian Perica" <perica@apple.com>
Received(Date): Wed, 11 Sep 2013 04:44:04 +0000

To: "Steve Hotelling" <shotelling@apple.com>, "Debbie Lambert"

<debbiel@apple.com>

Cc: "Steve Smith" <srsmith@apple.com>
Date: Wed, 11 Sep 2013 04:44:04 +0000

Steve,

Wow, we are so sorry for missing this thread. I just saw it. We should proceed with joint development with Masimo vs. M&A. I raised M&A with Tim. He's not interested given the overall product profile of Masimo.

### REDACTED

Thx

Sent from my iPad

On Aug 29, 2013, at 4:25 PM, Steve Hotelling <shotelling@apple.com> wrote:

Hi Adrian,

### REDACTED

Or perhaps there's a forum where we discuss the concept w' Jeff W. first, then decide if we proceed?

Thanks,

Steve

Begin forwarded message:

From: Steve Hotelling <shotelling@apple.com>

Subject: Fwd: Rover | 8/28

Date: August 29, 2013 4:16:31 PM PDT

To: Myra Haggerty <myra@apple.com>, Jack Fu <ifu@apple.com>

**Cc:** Debbie Lambert <<u>debbiel@apple.com</u>>, Steve Smith <<u>srsmith@apple.com</u>>, James Foster <<u>ihfoster@apple.com</u>>, Adrian Perica <<u>perica@apple.com</u>>, Brian Land <<u>bland@apple.com</u>>, Benjamin Lyon <<u>benlyon@apple.com</u>>

Hi Myra & Jack,





### 

See Rover notes below. I asked Debbie to invite you to future Rover meetings.

We had met w' Masimo several months back, and they seemed to have good knowledge of PPG and several associated algorithms for motion rejection.

My impression was that while I suppose much of their business focus is different from ours, they may have PPG algorithm technology (and HW technology?) that might accelerate our effort for N27A. Brian Land & James Foster, what was your impression?

One scenario that I'd suggest we consider would be an engineering collaboration agreement where we expose them to our N27A Platinum effort, get access to their algorithms and experts, ideally have a team of them work directly with us, perhaps in Cupertino, look at the actual signals from our hardware and help us make the best extraction algorithms possible. They might help consult on our hardware, especially if they have also tried using multiple optical paths to first-order reject motion artifacts (I think they do use multi-wavelengths to reject motion artifacts). They might also consult on our testing methodology, and they may know of how to find worst-case users / situations.

We might ask for some exclusive window of time where they enable only Apple for consumer electronic, non-prescribed, watches. In return, we could offer them NRE, and ...? (not sure exactly what they want, but perhaps we have something we could provide for them).

Mike O'Reilly used to work there, and he thought they would likely have engineers & scientists who had been working on PPG and motion artifact rejection for many years, who may be able to inform us of some of the approaches they tried historically, some of the hurdles they faced, what worked and what didn't, etc.

Steve & Adrian, I can't remember how we left it with them. What are your thought on this, and next steps?

Thanks,

Steve

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Begin forwarded message:



Stanford Alumni Mail - The three equations

11/24/18, 11:30 AM



M. Lamego Exhibit 301 (5-20-21)

### The three equations

Marcelo Lamego <a href="mailto:mminego@stanfordalumni.org">mminego@stanfordalumni.org</a> To: tcook@apple.com Wed, Oct 2, 2013 at 12:54 AM

Dear Tim Cook.

I was approached by Apple in the beginning of this year (by David Affourtit and James Foster) and was asked if I would like to join the executive technical team. Because I did not want to sign the Apple's NDA for an onsite interview, the process came to a halt. I felt that it was not appropriate to receive confidential information from or disclose confidential information to Apple given my fiduciary responsibilities as the Chief Technical Officer of Cercacor.

I have developed several medical devices in the last 10 years and I am positively sure I could add a significant value to the Apple team, if I was given the chance of becoming part of it in a senior technical executive position and without conflicting with the large IP I have developed for Masimo and Cercacor during the same period.

What I am sure Apple soon will realize is that medical, wellness and fitness technologies are very deceptive in the sense that they are easy to develop for products that work in most (~80%) he users. Getting the same technology to work in almost the entire population is a problem extremely more complex. This is the very reason most medical device startups become insolvent. Knowing Apple's reputation, I am sure you would not settle for even 99%, imagine then, 80%.

As you probably know, regulatory barriers are another important consideration when dealing with medical technologies in general. If the FDA or any other regulatory agency worldwide (i.e., Canada, Japan, Korea, Europe, etc.) believe your product should be regulated by their standards then, the choice of intended use combined with the technology realization strategy can make the development shorten or longer by several years.

The reason I feel attracted by Apple as a company is not related to the things most people are interested in, i.e., brand recognition, great culture, great products, great people. It has to do with the fact that, as an engineer, I realized that there are three important equations to be solved in order to create a competitive global medical, wellness and fitness product portfolio:

- (i) The user equation Apple has solved it and created the industry standard. With a brand recognition similar to the ones from luxury products, everybody is interested in understanding and using Apple's intuitive interfaces.
- (ii) The patient equation This is the deceptive part.
- The connectivity equation This can only be solved with scale and brand recognition, which e synonymous for Apple. Reliable wireless technology and device interoperability will become a must in the medical device segment.

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Page 1 of 2



MLAMEGO0000061



- Stanford Alumni Mail - The three equations

11/24/18, 11:30 AM

I believe Apple has solved (i) and has enough resources to solve (iii). I can help you to solve (ii).

J puld appreciate if the content of this letter could be kept confidential, since it can jeopardize outcome of my career at Cercacor.

I strongly believe that we can develop the new wave of technology that will make Apple the number one brand in the medical, fitness and wellness device market. If you agree, feel free to contact me anytime.

All the best,

Marcelo Malini Lamego

18 Lyra Way

Coto de Caza CA 92679

Home phone: (949) 216-9294

My resume is available at http://www.linkedin.com/pub/marcelo-lamego/54/644/725

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MLAMEGO0000062

- Stanford Alumni Mail - Apple

11/26/18, 9:09 PM



### Apple

David Affourtit <affourtit@apple.com>
To: Marcelo Lamego <mmlamego@stanfordalumni.org>
Co: Denby Frazier <denby@apple.com>

Wed, Oct 2, 2013 at 10:25 AM

Hello Marcelo,

Thank you for your voicemail and follow up. I saw your note to Tim Cook. I'm glad you remain enthusiastic about Apple.

As I've transitioned out of the Exec Recruiting team into a management role, I've asked my associate from the Exec Recruiting team to reach out to you directly. Her name is Denby Frazier, cc'd.

Denby, meet Marcelo, Marcelo, Denby.

All the best and thanks again!

Cheers, Dave

https://mail.goog/e.cern/mall/u/0?ik=4082d4e25e&view=pt&search...msg-f%3A1447805301648269504&simpl=msg-f%3A1447805301648269504

Page 1 of 1

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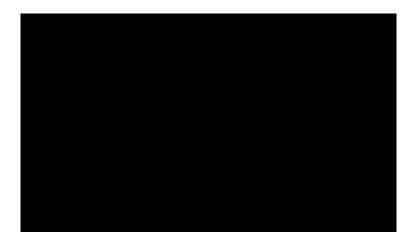


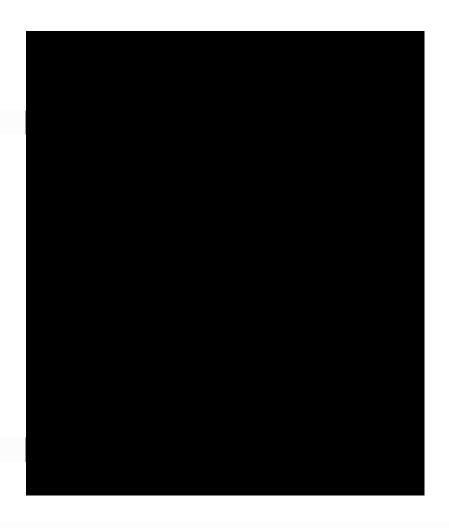
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Exhibit O Page 1

	Everest   Purpose			
	<ul> <li>Decide how to engage Masimo of respect to the PPG sensor in Nx</li> </ul>	Corporation and/or Cercacor with x		
	<ul> <li>Discuss Mike O'Reilly's involvement in negotiating the deal and how/ when to respond to the recent inquiry by the CTO of Cercacor</li> </ul>			
19	ple PHWeged & Corlidornial	1	10,02,01	
				APL-MAS_01853760







### Masimo | Pulse Oximetry Competitive Landscape

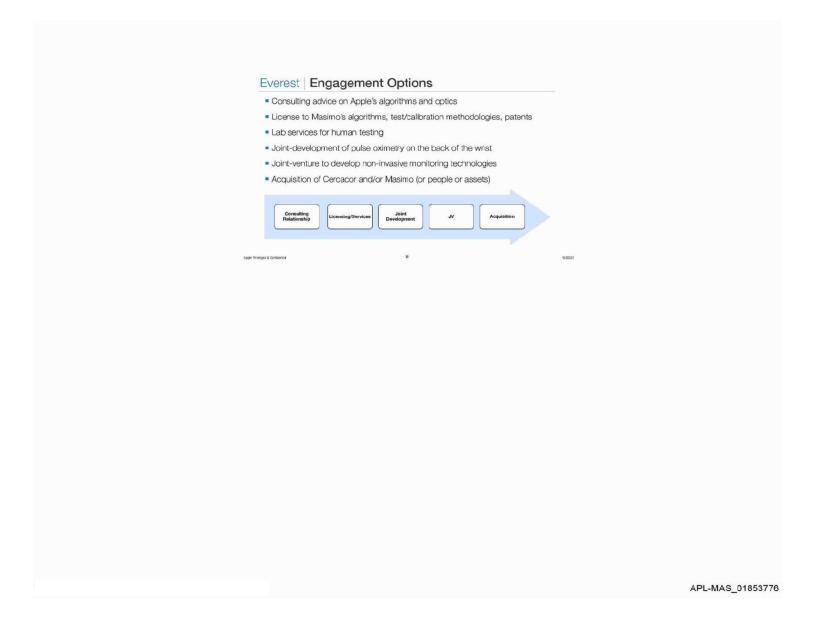
Company	Medical-Use Only	Consumer-Focused	Comments
Masimo	¥	*	-49% market share based on \$1B market; consumer product is iOS device
Covidien/Nallcor	√		Masimols CEM partner
GE Medical	<b>√</b>		Masimo's CEM partner
Mindray	<b>√</b>		Masimo's CEM partner
Nonin	1		Pioneer in pulse eximetry; private company
Philips	J		Masimo's CEM partner
Mio Alpha		<b>√</b>	Underlying technology provided by Philips
Zensorium		1	Singapore-based startup; Backed by Nitto Denko (Japanese Specialty Chemicals Company)

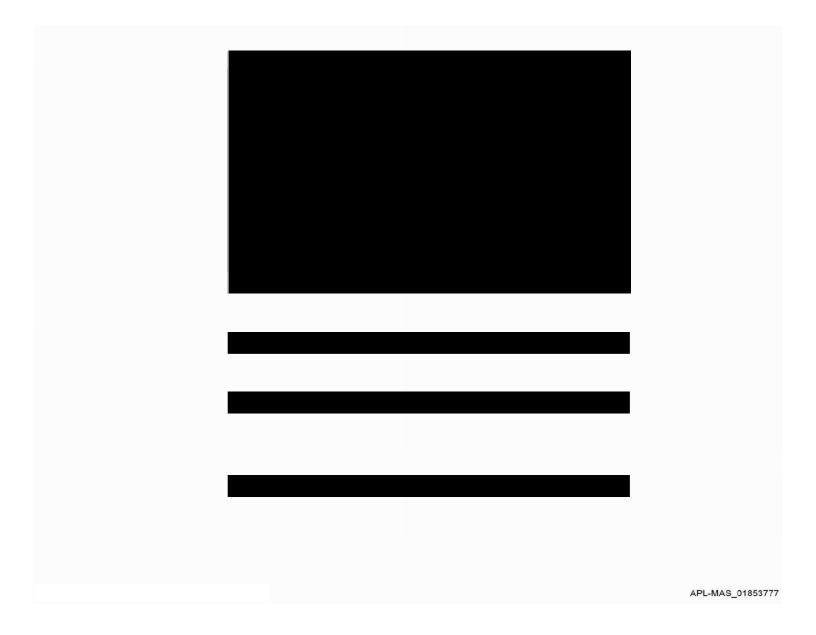
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### Everest | Potential Collaboration

Apple Requests	Masimo Requests
Review of Apple algorithms	Better integration with iOS devices
Review of optical characteristics	Royalties
Testing methodologies	Co-branding / co-marketing
LED calibration techniques in MP	Contribution to Masimo Foundation and/or patien safety causes
Access to labs for human testing (e.g. to develop SPO <sub>2</sub> calibration curves)	
Physiology and performance expertise	

ope Privileged & Controllar





Even	est   Marcelo Options	
① ② ③ ④	Don't hire Marcelo  Hire Marcelo after signing a deal  Hire Marcelo during negotiations  Hire Marcelo before starting negotiations	
Jugar Privileges & Confidentia	,	198829
		APL-MAS_01853778

Subject: Re: Recruiting from Masimo

From: "Lan Nguyen" <a href="mailto:slan.nguyen@apple.com">lan.nguyen@apple.com</a>

Received(Date): Wed, 04 Dec 2013 09:20:33 +0000

To: "Steve Hotelling" <shotelling@apple.com>

Date: Wed, 04 Dec 2013 09:20:33 +0000

Thanks Steve,

I'll plan on scheduling for us to get together early next week when you return.

On Dec 3, 2013, at 4:53 AM, Steve Hotelling <shotelling@apple.com> wrote:

Hi Lan.

- 1) Myra or Jack should be there (Myra is OOO next week)
- 2) Me or (Marty and Benjamin)

Either late this week or early next week is fine with me.

Thanks,

Steve

On Dec 3, 2013, at 4:32 AM, Lan Nguyen < lan.nguyen@apple.com > wrote:

### Hi Steve.

I have the last phase of this confidential project ready to present to you & Myra. I know you and Lynn are traveling this week. Would you prefer for me to invite Marty and Benjamin from your team to review this next batch or would you prefer to wait until next week when you and Lynn return to review this?

Thanks!

-Lan

On Oct 29, 2013, at 9:57 PM, Lan Nguyen < lan.nguyen@apple.com > wrote:

Hi Steve,

Our research team informed me that they should have a small portion of the research ready for us to view by end of this week. I will set up a meeting for us to look through the research once they send it over to me (& will include Lynn/Myra as well).



т	h	а	n	ks	١

On Oct 22, 2013, at 12:44 PM, Steve Hotelling <shotelling@apple.com> wrote:

Thanks, Lan, sounds good.

Yes, please see if you can expedite. Could be an in-progress review in a week followed by another one later on?

Thanks,

Steve

On Oct 22, 2013, at 12:09 AM, Lan Nguyen <a href="mailto:slan.nguyen@apple.com">lan.nguyen@apple.com</a> wrote: Hi Steve,

Wanted to give you a quick update on this. We're currently working on researching next level down as discussed and as soon as I have information on both companies, I will pull a meeting for you, Myra and Lynn to review what we find. Our research team needs a couple of weeks to get this done (if you think we need it sooner than this, please let me know and I'll see if we can expedite.) I'll keep you posted as soon as I have more concrete data to present.

Thanks!

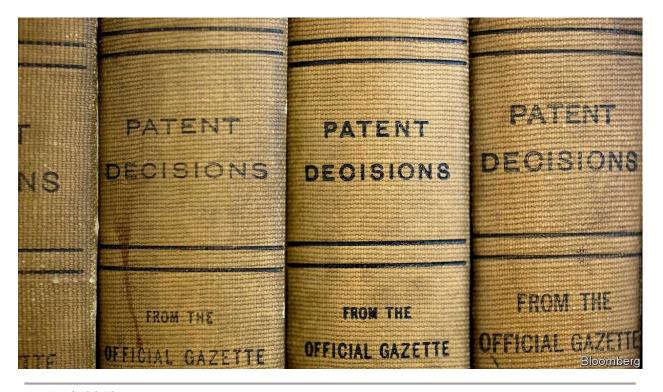
-Lan

Redacted

# **EXHIBIT 46**



Rules to curb frivolous patent claims may encourage infringement



Dec 14th 2019 NEW YORK

Nucurrent, a startup in Chicago, has come up with a way to charge electronic gizmos wirelessly—a nifty trick for devices such as smartphones. So nifty, in fact, that Samsung, a giant South Korean device-maker, uses it in its mobile phones—or so NuCurrent claims. In 2018 NuCurrent sued Samsung in America for using its technology without paying royalties. In February Samsung denied NuCurrent's allegations in a court filing. Then, between March and June, it filed seven legal challenges against NuCurrent's patents. Navigating each will cost NuCurrent between \$500,000 and \$1m, says its boss, Jacob Babcock—a lot of money for a firm with 35 employees and no in-house lawyers.

Predicaments like Mr Babcock's are increasingly common. Paul Michel, a former top judge on America's patent court, attributes them to an "unco-ordinated overcorrection" to the plague of patent trolls, who accumulate patent rights with an eye to extorting payments

from supposed infringers. To fight them, America's government has weakened some intellectual-property protections, notably by reducing the threat of an injunction to block sales of the technology in question. In 2012 it created the Patent Trial and Appeal Board (ptab) to hear retrospective challenges to a patent's validity. And Supreme Court rulings have made it easier to prove patents invalid by narrowing the criteria for what constitutes an eligible patent.

The well-meaning rules appear to have beaten back the trolls; the number of patent disputes this year is down 37% from 2015, according to Unified Patents, a research firm. The ptab has invalidated thousands of patents. But the reforms have strengthened the position of big firms in relation to the little guy, say entrepreneurs and venture capitalists. Christopher Coons, a Democratic senator critical of the rule changes, has spoken of a "steady erosion of patent rights". Worse, Mr Coons has argued, they create perverse incentives for big companies to flout patents. Boris Teksler, Apple's former patent chief, observes that "efficient infringement", where the benefits outweigh the legal costs of defending against a suit, could almost be viewed as a "fiduciary responsibility", at least for cash-rich firms that can afford to litigate without end.

Samsung's fellow tech giants, including Apple, Google and Intel, have filed numerous patent-validity reviews. Big Tech is, predictably, firmly opposed to tougher rules, which Mr Coons and others have proposed. Supporters of strengthening note that weakened patent protection has coincided with a decline in the share of American venture capital going to patent-heavy fields like advanced manufacturing or medical technology, from 21% to 3% between 2004 and 2017, according to a study commissioned by the National Venture Capital Association, an industry body. Richardson Oliver Insights, a research firm, reckons the average value of an American patent traded in the secondary market fell by 58% from 2013 to 2018. Feebler intellectual-property rights may not be the sole explanation. But having long harrangued China for its disrespect of such rights, America now finds itself badgered, too.

This article appeared in the Business section of the print edition under the headline "The trouble with troll-hunting"

# **EXHIBIT 47**

Case: 24-1285 Document: 25-3 Page: 437

# Dying for an iPhone

Filed: 01/10/2024



APPLE, FOXCONN, AND THE LIVES
OF CHINA'S WORKERS

Jenny Chan, Mark Selden and Pun Ngai

#### Praise for Dying for an iPhone

"Dying for an iPhone is far and away the most comprehensive account of the lives and working conditions of the people who produce what is perhaps the iconic commodity of the twenty-first century—the iPhone. But it is much more than that. We also see how Apple and Foxconn, working within a neoliberal trade regime promoted by the US, Taiwanese, and Chinese governments alike, transcended national boundaries to develop a brutally exploitative system of labor discipline. It is an incisive account of the social dislocation, but also the resistance, wrought when capitalists of many nations unite against workers. Global in outlook while still presenting fine-grained and highly engaging accounts of workers' lived experiences, this book is a shining example of public scholarship."

-Eli Friedman, coeditor of China on Strike

"Critical, accessible, and rigorously researched, this book offers the most comprehensive analysis of Foxconn, the world's largest electronics factory: its bleak landscape, dire consequences, and inspiring efforts to change it for the better."

—Jack Linchuan Qiu, author of Goodbye iSlave: A Manifesto for Digital Abolition

"Holding a sleek new iPhone in our hands it is difficult to imagine the brutal work lives of the people who assemble our smartphones. In *Dying for an iPhone* Jenny Chan, Mark Selden, and Pun Ngai make this reality visible. Drawing on in-depth field work and a deep knowledge of the global electronics industry, the authors demonstrate not only the steep human cost of our love affair with smartphones, but also the fierce struggles by Chinese workers to improve their working conditions."

—Nicole Aschoff, author of The Smartphone Society: Technology, Power, and Resistance in the New Gilded Age "Dying for an iPhone takes readers deep inside the dark Satanic mills of Foxconn's industrial empire. Drawing on the words of the workers themselves, the book offers an invaluable portrait of the Chinese working class as it pumps blood (sometimes literally) into the productive heart of world capitalism."

-Ben Tarnoff, cofounder of Logic Magazine

"A deep dive into exploitation and labor struggle in the world of high-tech electronics manufacturing in China during the past decade. *Dying for an iPhone* is an exposé of the human suffering behind the brands. Everyone should read this."

-Hsiao-Hung Pai, Taiwanese journalist

"Dying for an iPhone is an absolutely necessary read for anyone seeking to understand the realities of modern-day capitalism. Contrary to the mythology of Silicon Valley, this carefully researched book explains why companies like Apple owe their success more to exploitation than to innovation."

—Wendy Liu, author of Abolish Silicon Valley: How to Liberate Technology from Capitalism

"A sobering investigation into the human, social, and environmental costs of producing the devices we have come to rely on, a process in which both corporations and we, the consumers, are complicit."

-Nick Holdstock, author of Chasing the Chinese Dream

"When reading chapters describing the assembly line experience of workers, and the scientific management system, I could only compare it to the chapter in Marx's Capital, when we are taken into the hidden abode of production. Dying for an iPhone is truly a great achievement to present such incisive description and analysis in a highly readable and accessible form."

—Jeffery Hermanson, International Union Educational League Case: 24-1285

# **iPhone**

APPLE, FOXCONN, AND THE LIVES OF CHINA'S WORKERS

Jenny Chan, Mark Selden, and Pun Ngai



Haymarket Books Chicago, Illinois

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#### **Preface**

To die is the only way to testify that we ever lived. Perhaps for the Foxconn employees and employees like us, the use of death is to testify that we were ever alive at all, and that while we lived, we had only despair.

-A Chinese worker's blog, May 27, 2010<sup>1</sup>

It was in January 2010 that we first heard about the suicides of workers at the Foxconn electronics plant in the Chinese city of Shenzhen, adjacent to Hong Kong. In subsequent months, we closely followed reports—dubbed the "suicide express" in the media. After "the 9th Foxconn jumper" committed suicide on May 11, several university researchers and students, including the authors, discussed what might be done to prevent more suicides. One week later, we joined others to issue a public statement calling on Foxconn, the Chinese government, and the All-China Federation of Trade Unions to act decisively to end the "chain of suicides." The statement read:

From the moment the new generation of rural migrant workers step beyond the doors of their houses, they never think of going back to farming like their parents. The moment they see there is little possibility of building a home in the city through hard work, the very meaning of their work collapses. The path ahead is blocked, and the road to retreat is closed. Trapped in this situation, the workers face a serious identity crisis and this magnifies psychological and emotional problems. Digging into this deeper level of societal and structural conditions, we come

FII6d: 01/10/2024

closer to understanding the "no way back" mentality of these Foxconn employees.<sup>2</sup>

By December 2010, eighteen workers were known to have attempted suicide at Foxconn facilities. Fourteen were dead. Four survived with crippling injuries. They ranged in age from seventeen to twenty-five—all were rural migrants in the prime of youth, emblematic of the new Chinese working class.<sup>3</sup>



The large banner on the ground reads, "What is the price of flesh and blood?" The banner on the top right says, "Dreams shattered." Demonstrators in Taipei placed flowers to commemorate the Foxconn worker victims on May 28, 2010.

Foxconn's parent company, the Hon Hai Precision Industry Company, was established by Terry Gou in Taiwan in February 1974. The trade name Foxconn alludes to the corporation's claim to produce connectors at fox-like speed. Within four decades, Foxconn would evolve from a small processing factory to become the world leader in high-end electronics manufacturing with plants extending throughout China and, subsequently, throughout the world. Foxconn has more than two hundred subsidiaries and branch offices in Asia, the Americas, and Europe.

As Foxconn strives to dominate global electronics manufacturing and advanced technology, its aspirations align with China's goal to

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#### Preface

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become the world's economic and technological superpower. Foxconn has achieved stunning growth through a combination of shrewd business practices, mergers and acquisitions, patent acquisition, and astute cultivation of relations with the Chinese government.

The company's claims go beyond its technology: "Hon Hai / Foxconn's commitment to continual education, investing in its people long term and localization globally not only leads to the deep collaborating relationships with leading institutions of higher learning, but also helps to make Hon Hai / Foxconn the largest exporter in Greater China and the second-largest exporter in the Czech Republic." Foxconn, with nearly one million workers—the vast majority of them in mainland China—is the world's largest industrial employer. But what precisely are Foxconn's priorities, and is a "commitment to continual education, investing in its people long term" among them?

China remains the heart of Foxconn's global corporate empire and its profitability. In 2018, Foxconn accounted for 4.1 percent of China's total imports and exports,6 with revenues topping US\$175 billion-or, in the currency of the New Taiwan dollar, TWD 5.2 trillion.7 The company's claims are grandiose: "Foxconn is a global industry-leading manufacturer of Computer, Communications and Consumer Electronics (3C) components." Focusing on "Cloud Computing, Mobile Devices, Internet of Things, Big Data, Artificial Intelligence, Smart Networks, Robotics/Automation, Foxconn has built sophisticated capabilities around key Industrial Internet technologies."8 Indeed, Foxconn has striven to move from low value-added processing and manufacturing to more profitable businesses and services, harnessing the power of intellectual property and technical invention. Where others have focused on these issues, we repeatedly return to gauging the corporation's rise as it affects its one million employees, the great majority of them rural migrant workers.

#### Apple, Foxconn, and Chinese Workers

Foxconn's largest customer by far is Apple. But its clients are a Who's Who of global electronics corporations, among them Alphabet (formerly Google), Amazon, BlackBerry, Cisco, Dell, Fujitsu, GE, HP, IBM, Intel, LG, Microsoft, Nintendo, Panasonic, Philips, Samsung, Sony, and Toshiba, as well as such leading Chinese firms as Lenovo, Huawei, ZTE, and Xiaomi. Foxconn assembles iPhones, iPads, iPods, Macs, TVs, Xboxes, PlayStations, Wii U's, Kindles, printers, and myriad digital devices. While primarily contracting for global electronics firms, Foxconn also produces a variety of products under its own name. The company looks to a future in which its major growth areas center on Foxconn brands operating at cutting-edge technological frontiers led by robotics and artificial intelligence. It is a future with profound implications for its labor force, the world economy, and geopolitics.

Apple and Foxconn are independent companies, but they are inextricably linked in product development, engineering research, manufacturing processes, logistics, sales, and after-sales services. By the end of the 1990s, Apple had exported all of its US-based manufacturing jobs and some of its research facilities overseas. Apple only retained a small number of workers and staff at its Macintosh computer factory in Ireland. This outsourcing means that Apple's success is inseparable from the contributions of its international suppliers and their workers, above all Foxconn and its Chinese employees.

The Apple mystique has centered on its rapid rise to a hegemonic position in the design and marketing of a range of electronics products led in recent years by the iPhone, and the aura surrounding Steve Jobs (1955–2011), its cofounder and for decades its dominant presence. Tim Cook, who succeeded the late Steve Jobs as Apple CEO in August 2011, is hailed by journalist Leander Kahney as "the genius who took Apple to the next level." Overshadowed in that American success story are the lives and welfare of the mainly Chinese workers who produce the products

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of the global megabrand that so many long to possess, and the relationship between Apple and Foxconn that sets the parameters of factory life.

#### Dying for an iPhone

Dying for an iPhone has a double meaning. A new generation of workers is struggling to meet corporate requirements for speed and precision in producing iPhones and other high-tech products precisely at a time when consumers around the globe are queuing up to buy the newest models. Apple's success is intimately bound up with the production of quality products at high speed. Given its control of the commanding heights of hardware, software, and design, Apple has remained in the driver's seat in setting the terms and conditions for Foxconn and, in turn, for its workers. As of 2010, Foxconn was the exclusive final manufacturer not only of iPhones for Apple, but also a major contractor of a wide array of electronics products for many other technology giants.

The suicide-prevention nets strung around Foxconn's China-based facilities and the barred dormitory windows in late May 2010—appearing at the peak of the suicide clusters and remaining ever since—serve to refresh collective memories about the despair that drove young workers to kill themselves, the companies' responsibilities for this tragedy, and collective efforts by workers and their supporters to create a more humane workplace.

#### A Collective Investigation in China

In summer 2010, we collaborated with researchers from China, Taiwan, and Hong Kong to conduct undercover research at Foxconn's major manufacturing sites in nine Chinese cities, mainly in southern, eastern, and northern regions: Shenzhen, Shanghai, Kunshan, Hangzhou, Nanjing, Tianjin, Langfang, Taiyuan, and Wuhan. Our goal was not just to look into the hidden abode of

Foxconn production on the ground, but also to assess the extent to which the Chinese state and global tech corporations fulfilled their responsibilities to protect workers in the context of transnational production.

In spring 2011, we returned to Foxconn's manufacturing bases in Shenzhen, where half a million employees were toiling day and night to make our smartphones, tablets, and many other electronics products. We also visited two emerging "Apple cities"—Zhengzhou in Henan province and Chengdu in Sichuan province—where Foxconn's new megafactories assembled iPhones and iPads, respectively, at wages well below those in the coastal areas that were the sites of older plants. Following capital movements and through multisited research, we witnessed Foxconn's rapid expansion across provinces with strong support by local governments, thereby creating a 24-hour, high-speed production network with more than forty industrial parks in China alone.

In December 2013, we wrote to Terry Gou, Foxconn founder and CEO, and Tim Cook, the CEO of Apple, describing the conditions our research had uncovered and expressing concerns about the well-being of Foxconn workers. In addition, we contacted the Foxconn Global Social and Environmental Responsibility Committee, the Apple Supplier Responsibility Program, and the Fair Labor Association (Apple was a member from January 2012 to October 2016). Our purpose was to gain corporate perspectives on issues that our research had uncovered: low wages and benefits, compulsory overtime, lack of fundamental health and safety precautions, abusive treatment of teenage student interns, and managerial repression of workers' attempts to press demands for securing rights guaranteed by employment contracts and national labor laws. While Apple and Foxconn paid close attention to the public relations challenges posed by strikes, fires and explosions, and worker suicides, our effort to engage the corporations in discussion of labor responsibility produced only corporate rationalizations and platitudes.11

Preface

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By contrast, workers would be far more responsive to our attempts to understand their lives. Our multiyear fieldwork, which continued to the outbreak of new coronavirus in the end of 2019, is based on interviews with Foxconn workers, student interns, teachers (who monitor the internship programs of their students), managers, and government officials, supplemented with field observations and extensive documentary research. Through interviews, poems, songs, open letters, photos, and videos shared with us, this book presents firsthand portraits of workers and teenage student interns—their hopes, dreams, and struggles to survive.<sup>12</sup>

#### Challenges to a Global Labor Regime

Foxconn is the king of the "electronics workshop of the world." While the company has achieved enormous wealth, it remains subordinate to the global brands, above all Apple, which sets the price and the volume of the orders placed with Foxconn and rival producers. In this competitive terrain, Foxconn is vulnerable to sweatshop charges as it seeks to meet the demands for quality and speed set by Apple and other brands. Not only Foxconn but also Apple and other brands may be named and shamed through labor strikes and walkouts as well as press criticism, undermining the corporate image with economic and reputational loss. In these circumstances, workers and their supporters may succeed in exploiting corporate social responsibility discourse to win public support for worker rights, at times appealing for consumer support at home and abroad, and force corporate compliance with legal and moral norms.<sup>13</sup> In particular, we recognize that universities—their students and faculties—are open to learning about and acting upon information about corporate abuses as many have taken part in social movements involving sneakers, sweatshirts, and other products that particularly catered to students and universities.

With the reintroduction of capitalist production methods since reform and opening-up, China in recent decades has been the

site of high levels of contentious politics with numerous worker strikes and protests. In key nodes of globalized electronics production, particularly in periods in which sales leaps are expected, such as the launch of new models, large-scale labor actions can send important messages to the state, to Foxconn, and to global brands, including Apple, sometimes contributing to worker gains. Officials, in the interest of maintaining social and political stability, serve as brokers to pressure companies into compromising with workers. However, workers who confront management, and, on occasion, the government and police, risk being charged with disrupting the social order and being fired and/or imprisoned.

Chinese labor relations remain unstable, prompting legal reforms that have meant to improve the lot of workers and to preserve the corporate-state nexus of power that demobilizes workers. Aggrieved workers oscillate between legal and extralegal tactics for resolving conflicts in order to draw attention and responses from the government, media, and the concerned public. Under the leadership of Xi Jinping from 2013, defiant workers, including Foxconn employees, have continued to protest abuses and fight to secure fundamental rights. Despite crackdown on nongovernmental organizations and human rights lawyers, they have persisted, at times with support from students and citizens. Should workers at Foxconn and elsewhere succeed in organizing and mobilizing effectively, they would inspire many more to strive to make a better future together.

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#### A Suicide Survivor

I was so desperate that my mind went blank.

—Tian Yu, a 17-year-old suicide survivor<sup>1</sup>

At about eight in the morning on March 17, 2010, Tian Yu threw herself from the fourth floor of a Foxconn factory dormitory. Just a little over a month earlier, she had come to Shenzhen city, the fast-rising megalopolis adjacent to Hong Kong that has become the cutting edge of development in China's electronics industry. While still a predominantly rural area when it was designated as China's first Special Economic Zone in 1980, Shenzhen experienced extraordinary economic and population growth in the following decades to become a major metropolis with a population exceeding 10 million by 2010, with nearly 8 million internal migrants from within Guangdong and other provices (who were also known as the "floating" population).<sup>2</sup>

Yu, who hailed from a farming village in the central province of Hubei, landed a job at Foxconn in Shenzhen. At the moment that she attempted to take her life, global consumers were impatiently waiting for the revamped iPhone 4 and the first-generation iPad. Working on an Apple product line of Foxconn's integrated Digital Product Business Group (iDPBG), Yu was responsible for spot inspections of glass screens to see whether they were scratched. An ever-shorter production cycle, accelerated finishing time, and heavy overtime requirements placed intense pressures on Yu and her coworkers.

Miraculously, Yu survived the fall, but suffered three spinal fractures and four hip fractures. She was left paralyzed from the waist down. Her job at the factory, her first, will probably be her last.





Tian Yu, half-paralyzed after jumping from the Foxconn Longhua factory dormitory, received treatment in the Shenzhen Longhua People's Hospital in Guangdong province.

#### Surviving Foxconn

Our first meeting with Yu took place in July 2010 at the Shenzhen Longhua People's Hospital, where she was recovering from the injuries sustained in her suicide attempt. Aware of her fragile physical and psychological state, the researchers were fearful that their presence might cause Yu and her family further pain. However, both Yu's parents at her bedside, and Yu herself when she awoke, put them at ease by welcoming their presence.

Over the following weeks, as Yu established bonds of trust with the researchers, she talked about her family background, the circumstances that led to her employment at Foxconn, and her experiences working on the assembly line and living in the factory

#### A Suicide Survivor

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dormitory. During interviews with Yu and her family, it became clear that her story had much in common with that of many Foxconn employees, comprised predominantly of the new generation of Chinese rural migrant workers.

"I was born into a farming family in February 1993 in a village," Yu related. What was recently a village is now part of Laohekou (Old River Mouth) city, which has a population of 530,000. Located on the Han River close to the Henan provincial border, it was liberated in the course of the anti-Japanese resistance of the 1940s. Following a redistributive land reform, in the mid-1950s, agricultural production was organized along collective lines. During the late 1970s, with the establishment of a household responsibility system in agriculture, followed in 1982 by the dismantling of the people's communes, farmland was contracted to individual households.

"At best my family could earn about 15,000 yuan on the land in a year, hardly enough to sustain six people. Growing corn and wheat on tiny parcels of land and keeping a few pigs and chickens might not leave us hungry," Yu said, "but making a better life is challenging if one seeks to eke out a living on the small family plot."

Yu belonged to the generation of "left-behind children" as both parents joined the early out-migration wave that enveloped China's countryside. Yu's grandmother brought her up while her parents were far from home supporting the family as migrant factory workers. Like many of the 61 million children who were left behind, she spent her early childhood playing with other neighborhood children.<sup>3</sup> There was little parental guidance. Eventually, her parents returned home to resume farming having earned just enough money to renovate the house. Yu, the eldest child, has a sister and a brother. She hoped, in the future, to be able to help look after her brother, who was born deaf.<sup>4</sup>

#### From Farm to Factory

China's accession to the World Trade Organization in 2001 brought about great challenges to villagers, who faced a flood of cheap subsidized crops imported from overseas even as export-driven industrialization expanded. Despite gains associated with the elimination of agricultural taxes in 2005 and the subsequent establishment of a social insurance scheme under the new socialist countryside campaign, as most young people departed for the cities and industrial jobs, the prospects for household-based agriculture and rural development generally darkened. Sporadic efforts toward cooperative rural construction and alternative development initiatives aside, opportunities for sustainable farming and lucrative nonfarm work in remote villages remained scarce.

After graduating from junior secondary school and completing a short course at the local vocational school, Yu decided to leave home to find a job. For her cohort of rural youth, the future, the only hope, lay in the cities. By 2010, TV and especially internet technology and mobile communications had opened a window on the real and imagined city lifestyle. "Almost all the young people of my age had gone off to work, and I was excited to see the world outside, too," Yu explained.

Soon after the Spring Festival, the Chinese New Year, in early February 2010, Yu's father gave her 500 yuan to tide her over while searching for work. He also provided a secondhand cell phone so that she could call home. He asked her to stay safe.

In the morning, "my cousin brought me to the long-distance bus station," Yu recalled of her departure for the city. "For the first time in my life I was far away from home. Getting off the bus, my first impression of the industrial town was that Shenzhen was nothing like what I had seen on TV."

On February 8, at the company recruitment center, "I queued up for the whole morning, filled out the job application form, pressed my fingertips onto the electronic reader, scanned my identity card, and took a blood test to complete the health check procedures."

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Yu was offered a job and assigned a staff number: F9347140. She also received a color-printed Foxconn Employee Handbook, which was replete with upbeat language for new workers: "Hurry toward your finest dreams, pursue a magnificent life. At Foxconn, you can expand your knowledge and accumulate experience. Your dreams extend from here until tomorrow."

Later, after a quick lunch, a human resources manager at an employee orientation told a group of new recruits, including Yu, "Your potential is only limited by your aspirations! There's no choosing your birth, but here you will reach your destiny. Here you need only dream, and you will soar!"

The manager told stories of entrepreneurs like Apple chief Steve Jobs, Intel chairman Andrew Grove, and Microsoft founder Bill Gates to inspire youthful new Chinese workers. Indeed, no less than Apple, Foxconn executives were masters of painting an idyllic future for workers and consumers.

"Then, I and hundreds of other new workers were taken from Foxconn's recruitment center to the factory, about an hour's ride on the company bus. The setting sun bathed the Foxconn facilities in golden light," Yu recalled.

#### Inside Foxconn

The gigantic Longhua "campus," as the Foxconn managers like to call it, organizes production and daily living activities in a densely populated environment. The complex includes multistory factories, dormitories, warehouses, two hospitals, two libraries, a bookstore, a kindergarten, an educational institute (grandiosely dubbed Foxconn University), a post office, a fire department with two fire engines, an exclusive television network, banks, soccer fields, basketball courts, tennis courts, track and field, swimming pools, cyber theaters, shops, supermarkets, cafeterias, restaurants, guest houses, and even a wedding dress shop. Container trucks and forklifts rumble nonstop, serving a grid of factories that churn

out iPhones and other electronics products for Apple and many global giants.

The factory directory displays a list of ten total zones—eight covering A through H, and two other zones labeled J and L—and they are further subdivided into A1, A2, A3, J20, L6, L7, and so on. It takes almost an hour to walk from the south main gate to the north main gate, and another hour to walk from the east to the west gate. Yu did not know what each building was, nor did she know the meaning of the English acronyms that could be seen written everywhere.

"I arrived late for my first day of work. The factory was so big, and I got lost. I spent a long time looking for the workshop," Yu said. When asked if she was scolded for being late, she answered so quietly that we could not hear her response.

#### Sisters or Strangers?

"I woke up at 6:30 a.m., attended a morning meeting at 7:20, started work at 7:40, went to lunch at 11:00, and then usually skipped the evening meal to work overtime until 7:40 p.m." On top of the "standard twelve-hour shift" during busy periods, like all other workers, Yu attended compulsory unpaid work meetings every day. "I reported to the line leader twenty minutes before the start of work for roll call. He exhorted us to maintain high productivity, reach daily output targets, and keep discipline."

A long workday of enforced silence, punctuated only by the noise of the machines, is the norm. Yu noted, "Friendly chit-chat among coworkers is not very common even during the break. Everyone rushes to queue up for lunch and eat quickly." In contrast to the corporate image of "a warm family with a loving heart," Foxconn workers frequently experience isolation and loneliness, some of it seemingly deliberately created by managerial staff to prevent the formation of strong social bonds among workers.

#### A Suicide Survivor

Managers, foremen, and line leaders prohibit conversation during working hours in the workshop. The assembly lines run on a 24-hour, nonstop basis, particularly when the production schedule is tight. The well-lit factory floor was visible throughout the night from afar. Yu felt that there was no way to say no to overtime.

New workers, like Yu, are often reprimanded for working "too slowly" on the line, regardless of their efforts to keep up with the "standard work pace." Emphasizing the company's claim to produce the world's best products for global customers, the maximum allowable rate of defective products is set low. Yu several times said that she had made no mistakes on the screens she worked on, but the line leader blamed her repeatedly for mistakes that she did not make.

With only a single day off every second week, or two rest days during the whole month, there was no spare time for Yu to use the Olympic-sized swimming pool or other recreational or educational facilities in "the factory city."

"I was switched to the night shift in March. Checking the screens of the products made my eyes feel intense pain," Yu told us.

#### Living in the Dormitory

Foxconn houses its employees in dormitories at or close to the factory. The workplace and living space are compressed to facilitate high-speed, round-the-clock production. The dormitory warehouses a massive migrant labor force without the care and love of family. Whether single or married, the worker is assigned a bunk space for one person. The "private space" consists simply of one's own bed behind a self-made curtain with little common living space.

Yu's roommates had jobs in six business groups and seven production departments. With roommates assigned from different departments and different shifts, and many speaking different dialects, it was difficult to socialize. When speaking of her roommates,

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Yu said, "We were not close." She then showed us the management record of her dormitory room.

Table 1.1 A Foxconn dormitory room list, 2010.

	Staff No.	Business Groups*	Production Departments	Dormitory Registration
1.	F9341932	NWInG	FKD	January 29, 2010
2.	F9450222	SHZBG	Mac BU (II)	March 18, 2010
3.	F9422526	CMMSG	AP (V)	March 10, 2010
4.	F9447733	CCPBG	TAMG TEAM	July 27, 2009
5	F9425127	CMMSG	IPPD LX (I)	March 10, 2010
6.	F9347140 [Tian Yu]	iDPBG	DSPG DSD LCM	February 8, 2010
7.	F9341960	NWInG	FKD	January 29, 2010
8.	F9295026	PCEBG	ABD (II)	December 21, 2009

<sup>\*</sup>NWInG (Net-Work Inter-Connection Business Group)

SHZBG (Super Hong Zhun Business Group, also known as Super Precision

Mechanical Business Group)

CMMSG (Component Module Move Service Group)

CCPBG (Consumer and Computer Products Business Group)

iDPBG (integrated Digital Product Business Group)

PCEBG (Personal Computing Electronics Business Group)

Note: Workers receive no explanation of the English acronyms of business groups or production departments.

Although eight young girls were housed in the same room, Yu explained, "We were strangers to each other. Some of us had just moved in as others moved out. None of the roommates was from Hubei." None spoke her dialect. Yu's father explained the significance of this: "When she first came to Shenzhen, sometimes when others spoke, she couldn't understand much."

"At Foxconn, when I felt lonely, I would sometimes chat online," Yu told us. But those chatting on the QQ instant messaging community often remain far apart in time and space. For factory newcomers from distant provinces, it takes a long time to develop a virtual friendship with mutual trust and shared understanding.

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#### The Accumulation of Despair

"After I had worked a month, when it was time to distribute wages, everyone else got their wage debit cards, but I did not." Yu was deeply troubled.

At Foxconn, the cash flow required for workers' wages is large and payment is done by a banking system through the provision of wage debit cards rather than paying cash to individual workers. A debit card is a bank card with which a worker can deposit, withdraw, and transfer money from 24-hour ATM machines that are accessible from within the Longhua complex and other Foxconn facilities.

Yu asked the line leader what had happened. Although she worked at Longhua, she was told that there was no record of her personal information at Longhua.

Unbeknownst to Yu, the Human Resources Department at Foxconn Guanlan had kept her personnel file and failed to transfer the documents to Longhua where she actually worked. She had been interviewed at the recruitment center in Guanlan before being sent to the Longhua facility. The result was that her debit card account at Foxconn Longhua had never been set up.

"I had no choice but to take a bus to Foxconn Guanlan on my own," Yu recounted.

The Foxconn factory in Guanlan subdistrict, which began production in 2007, employed 130,000 workers in early 2010. Entering an unfamiliar factory compound, Yu remembered, "I went to Block C10, B1, B2, and from floor to floor of building after building to inquire about my wage card." After a fruitless day of searching for the right office, with managers and administrators deflecting responsibility, Yu was unable to learn what had happened to her wage card or how to solve the problem. "I went from office to office by myself but no one would point me in the right direction. They all brushed me off, telling me to ask someone else."

Yu had not been paid for a month of work, approximately 1,400 yuan consisting of basic pay of 900 yuan plus overtime premiums.

By then it was the middle of March, and after more than one month in Shenzhen, she had spent all of the money her parents had given her. "Where could I borrow money? At this moment of crisis my cell phone broke, and I was unable to get in touch with my cousin in Shenzhen."

Yu had reached the breaking point. The exhausting assembly line, harsh factory discipline, and friendless dormitory, together with the difficulty she faced contacting her family, were compounded by the exhaustion of her funds and the company's failure to pay her. She felt overwhelmed.

#### One Life to Live

"I was so desperate that my mind went blank." In the early morning on March 17, Yu jumped from her dormitory building. After twelve days in a coma, she awoke to find that she had become paralyzed from the waist down.

Yu was hospitalized for more than six months. Finally Foxconn disbursed a one-off "humanitarian payment" to "help the Tian family to go home." It was a bid to end its responsibility over employee suicide and to remove the problem from the eyes of the Chinese and international press.

In the words of Yu's father, "It was as if they were buying and selling a thing."

When Yu left the hospital, she also left us with some troubling questions about the lives of one million Foxconn workers and the responsibilities of corporations and the Chinese government to protect workers.

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# **EXHIBIT 48**

Subject: Re: A bad new, a good new, and a thought ...

From: "Steve Waydo" <swaydo@apple.com>

Received(Date): Tue, 17 Mar 2020 16:58:19 +0000

To: "Xiao Jin" <xiao\_jin@apple.com>
Date: Tue, 17 Mar 2020 16:58:19 +0000

Hi Xiao,

Thanks so much for the feedback. I too was incredibly disappointed by the recent leaks, they went well beyond the usual (often supply chain-based) rumors and into "somebody is talking" territory:-/

You're right that there's a silver lining in reaffirming the excitement out there for the products we're building, and reinforcement of the importance of what we do. I tried to convey a little of this in my email last week (thanks for the inspiration!) and will continue to look for opportunities to communicate this with the team more.

Thanks again, and good luck with the WFH situation. Keep the ideas coming!

Best,

Steve

Steve Waydo — □ HID — 408.596.6998 swaydo@apple.com

> On Mar 12, 2020, at 10:42 AM, Xiao Jin <xiao\_jin@apple.com> wrote:

> > Hi Steve,

> As you may have learned, 9to5Mac recently announced that iOS 14 was leaked and many features were exposed, including Scandium. I was rather astonished that iOS 14 was leaked so early and the list of exposed features was very long and a lot of which were news to me lol. Quite a bad new.

>

> However, I do think there is silver lining. As I read more of the comments and discussion on those websites (yes, one cannot resist to learn what people think about the new features), it seems that Scandium is a well received feature. There are comments that say they would buy an Apple Watch if the rumor of blood oxygen feature is real and some say they would switch from Fitbit to Apple Watch if that is true, especially during the chaos of COVID-19 and many are looking into buying a blood oxygen monitoring device.

>



> A thought after digesting the news. These comments following the leak make me more proud and encouraged to work on a better Scandium product, which was a key reason why I have been in the healthcare industry since grad school. I think internally it also helps to remind ourselves what we are doing makes a difference in helping people. The emails from Tim and Jeff you have been forwarding to us are very good examples at your level. If I could recommend, maybe at your staff level, the same thought of why we are doing what we do can be shared with the team members. I think it may help encourage the teams understand the importance of the level of details and number of iterations that we work on.

> Thanks for your attention and happy WFH (hope you are also able to).

> > Xiao

# EXHIBIT 49

Video file submitted on a physical thumb drive